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(54) **EXTRACTABLE FILLER FOR INSERTING
MEDICINE INTO ANIMAL TISSUE**

(75) Inventors: **Kwan Ku Lin**, Pasadena, CA (US);
Philip S. Yuan, Fayetteville, NY (US)

(73) Assignee: **Crosstrees Medical, Inc.**, Boulder, CO
(US)

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(52) **U.S. Cl.** **606/86 R**; 604/500; 604/60

(58) **Field of Classification Search** 604/57-64,
604/93.01, 500, 502; 606/92-94, 86; 623/17.12
See application file for complete search history.

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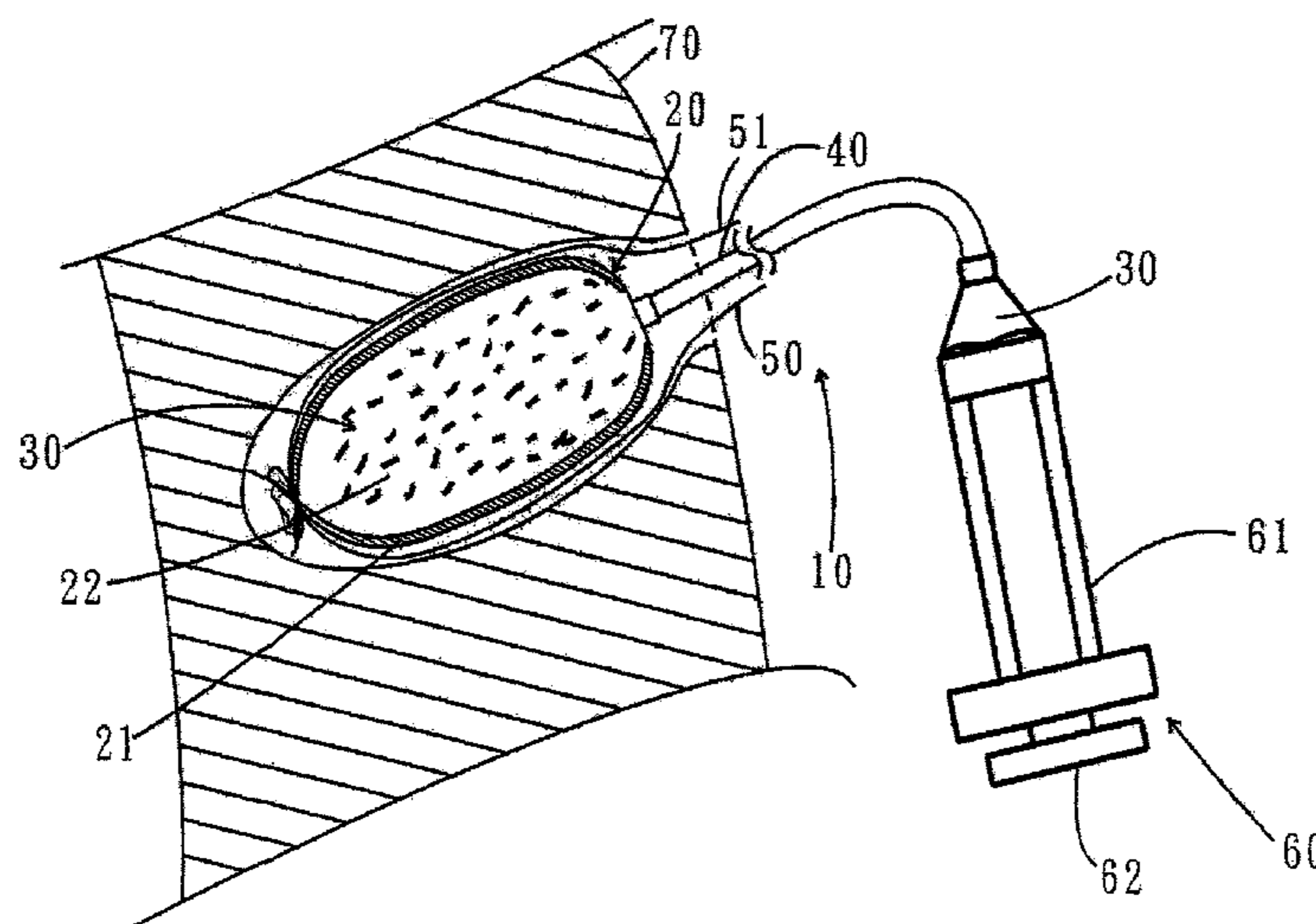
Primary Examiner — Theodore J Stigell

Assistant Examiner — Catherine N Witczak

(57) **ABSTRACT**

An extractable device is used to insert a medicinal filling into an animal tissue. The device comprises a filling member and a pasty medicine. The filling member is made of a flexible and permeable wall and is provided with a holding portion and an injection port via which the pasty medicine is injected into the holding portion after the filling member is inserted into the animal tissue. The holding portion is provided with an opening which is releasably lashed by one end of one or more threads so as to make the opening leakproof. Upon completion of solidification of the pasty medicine in the holding portion of the filling member, other end of the thread is pulled to unlash the opening of the holding portion, thereby enabling the filling member to be extracted from the animal tissue so as to leave only the medicine in the animal tissue.

17 Claims, 16 Drawing Sheets



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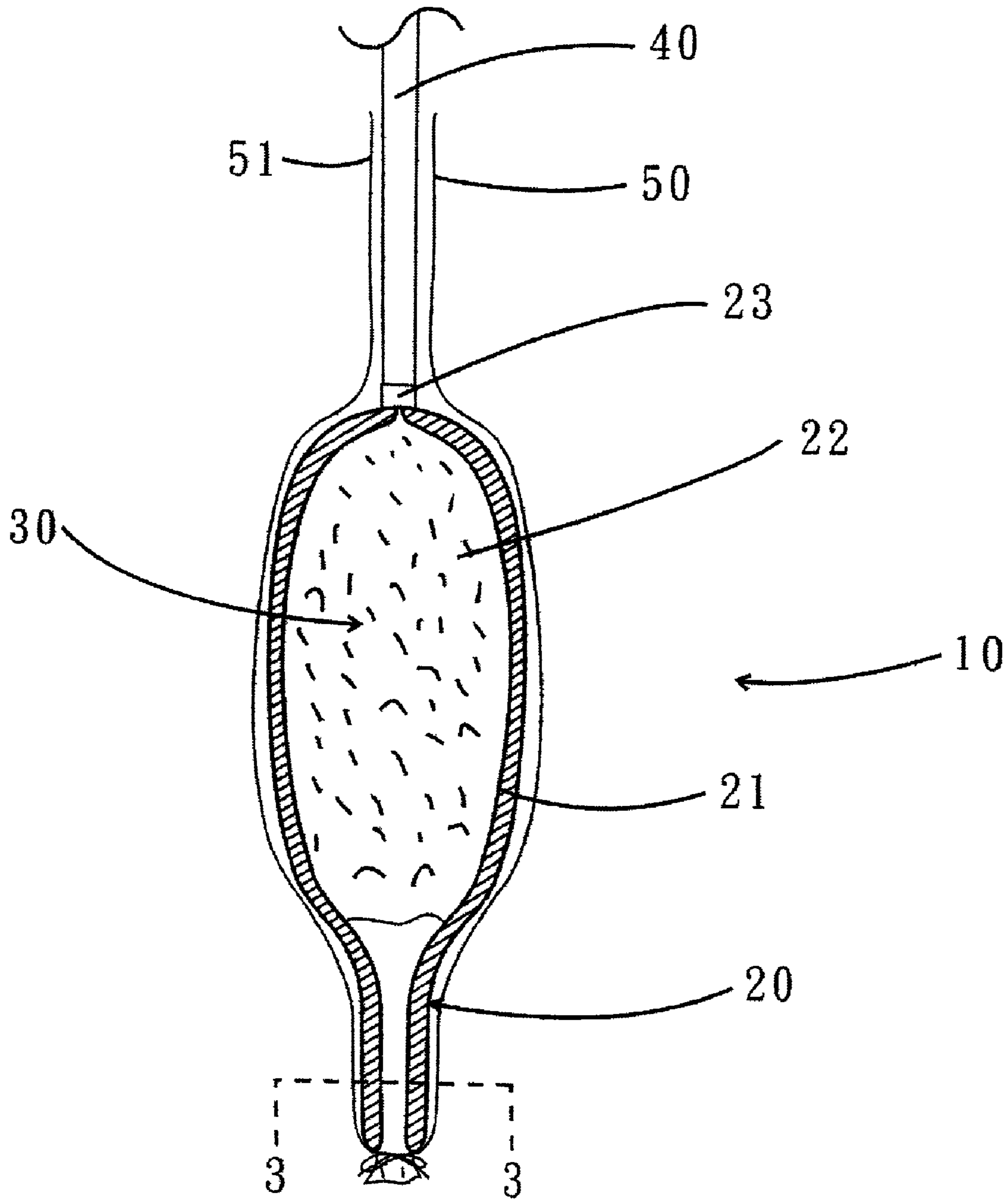


FIG. 1

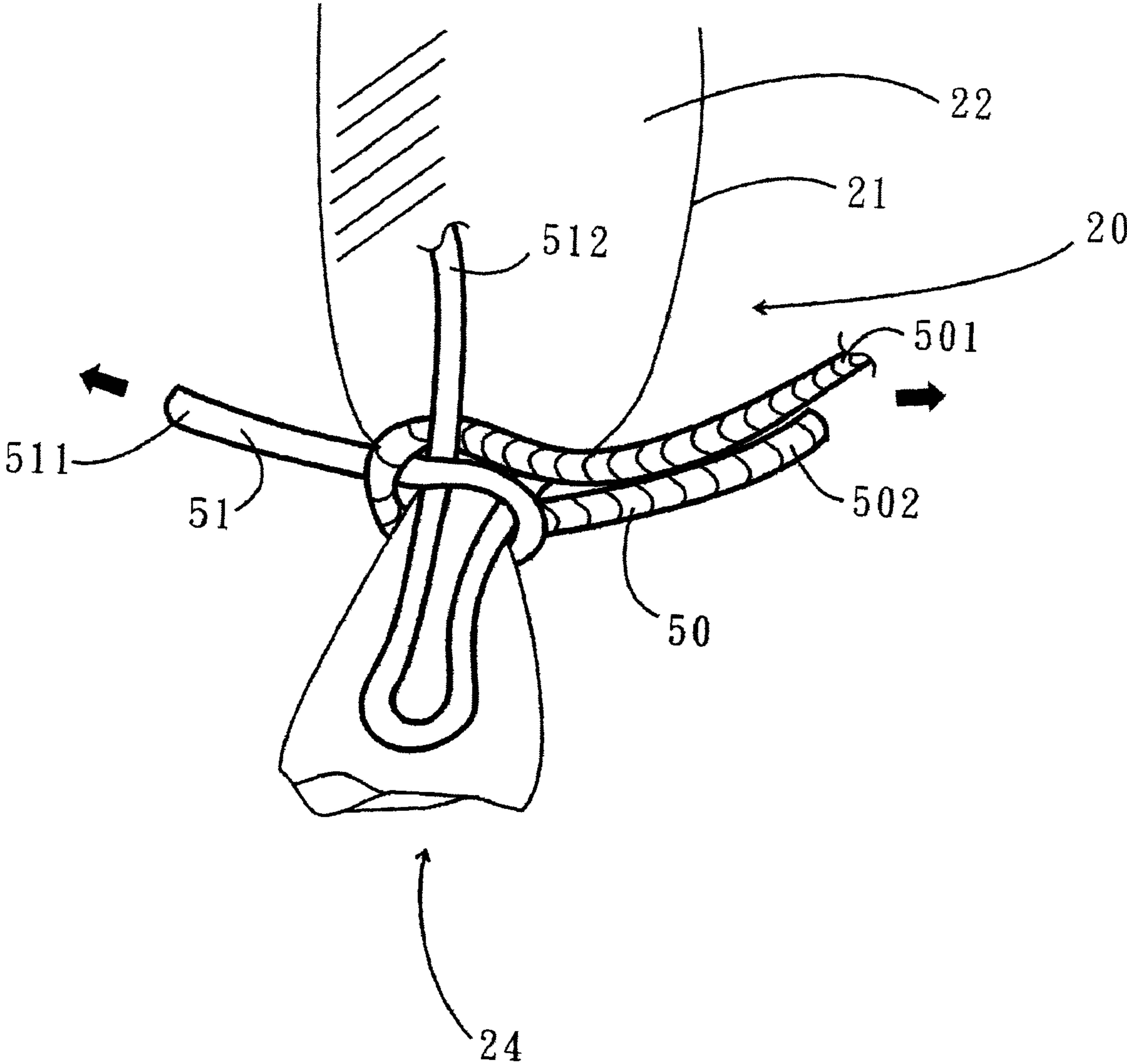


FIG. 2a

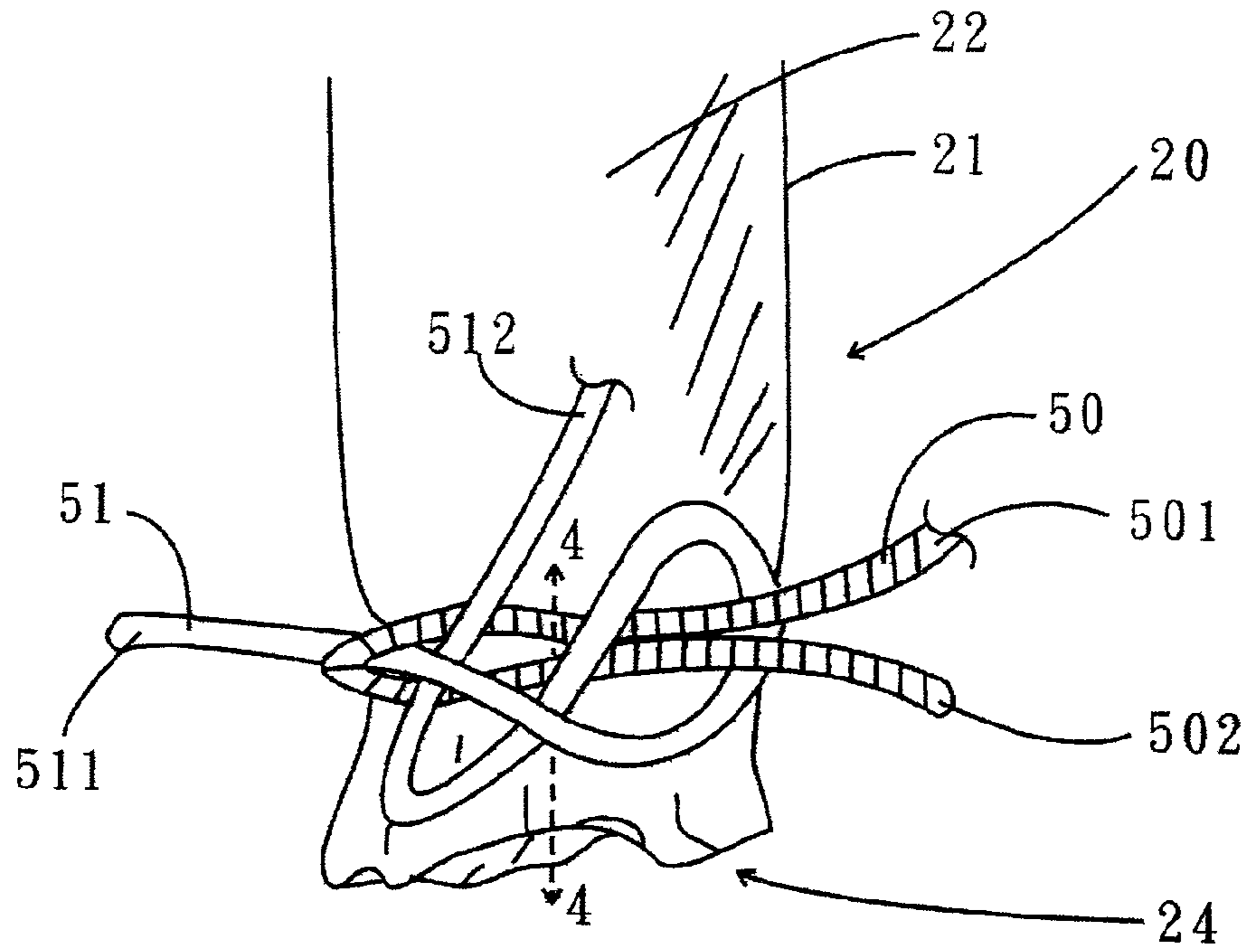


FIG. 2b

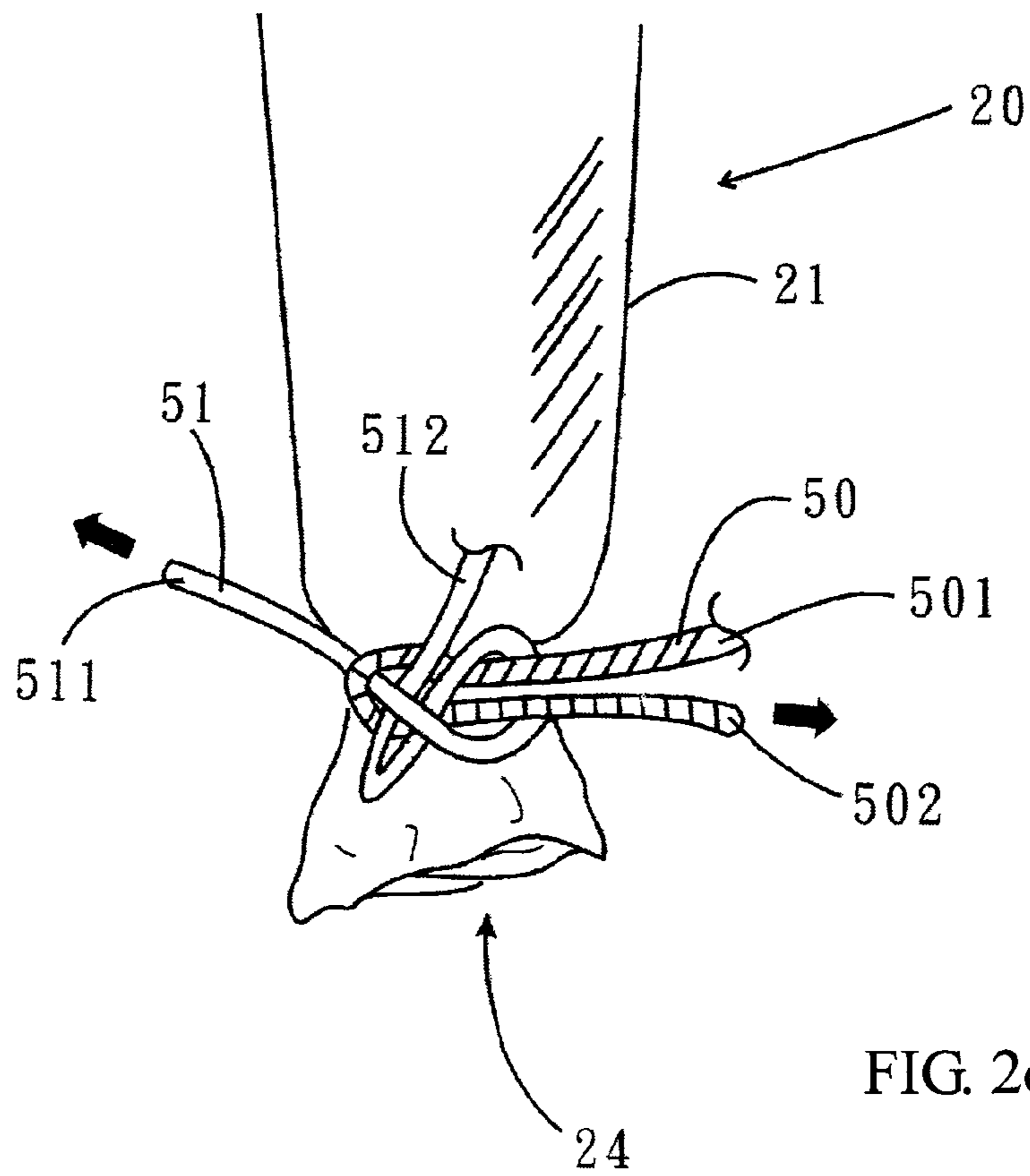


FIG. 2c

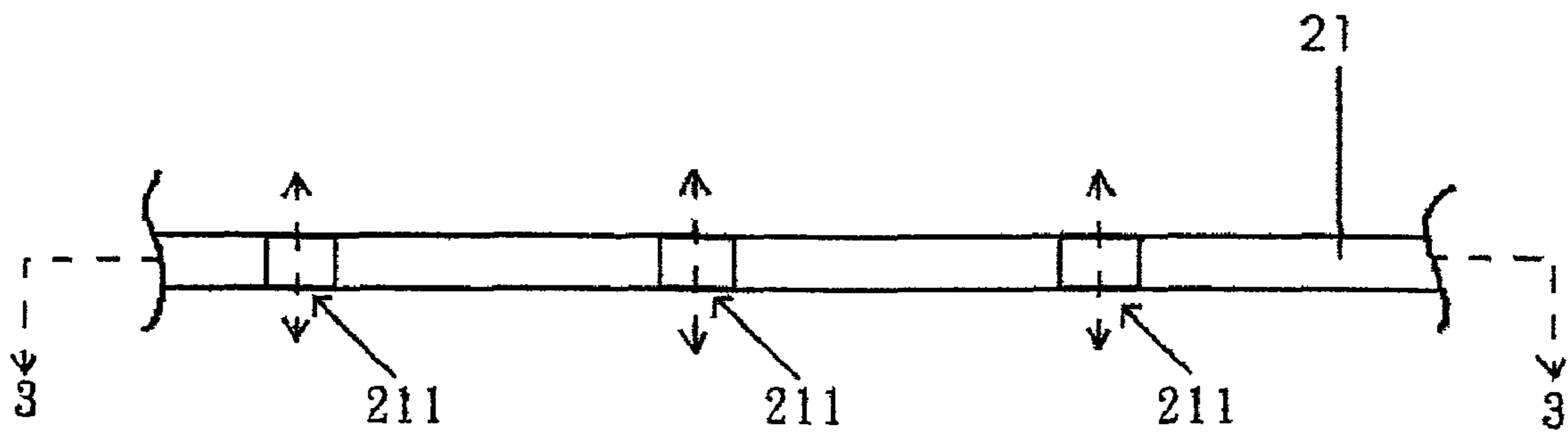


FIG. 3a

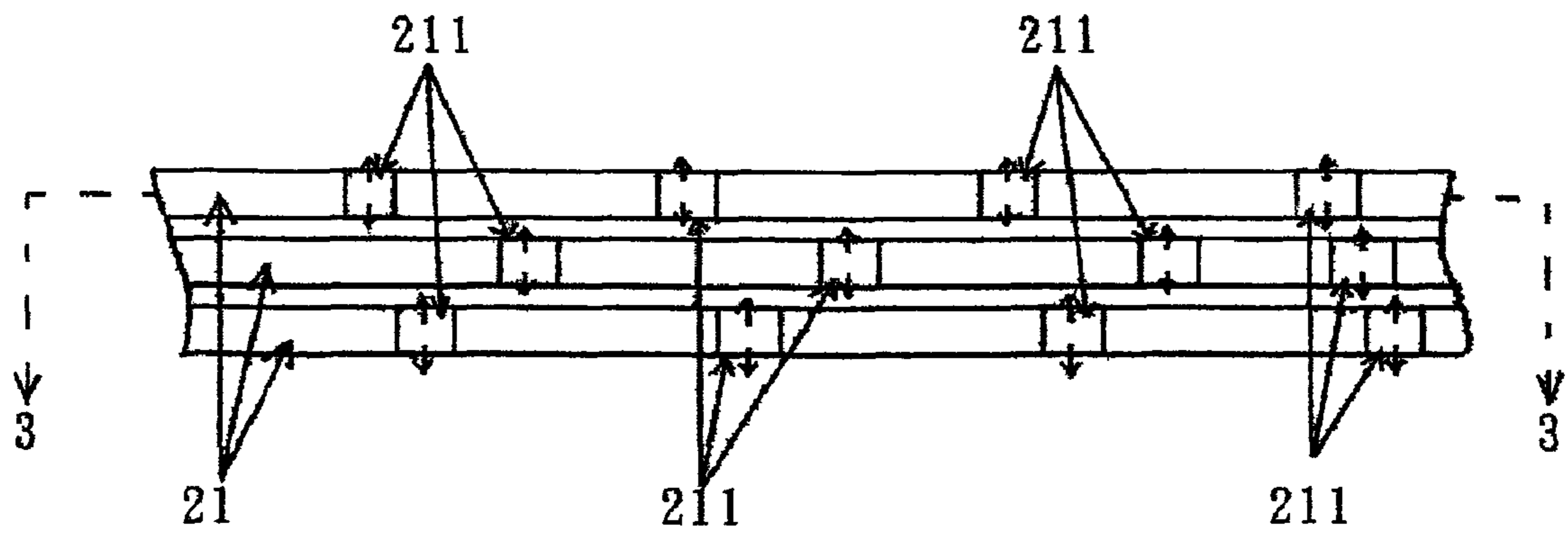
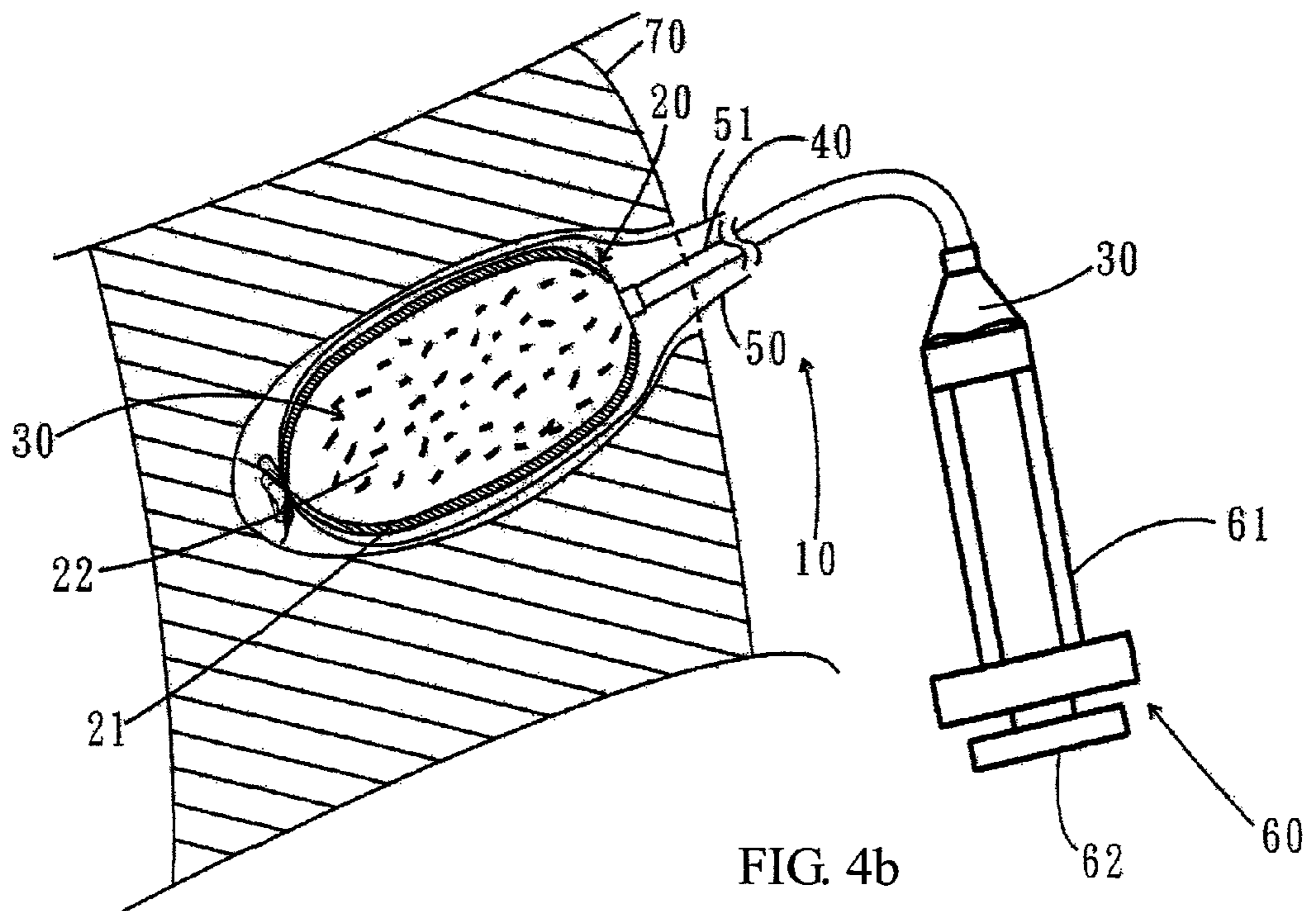
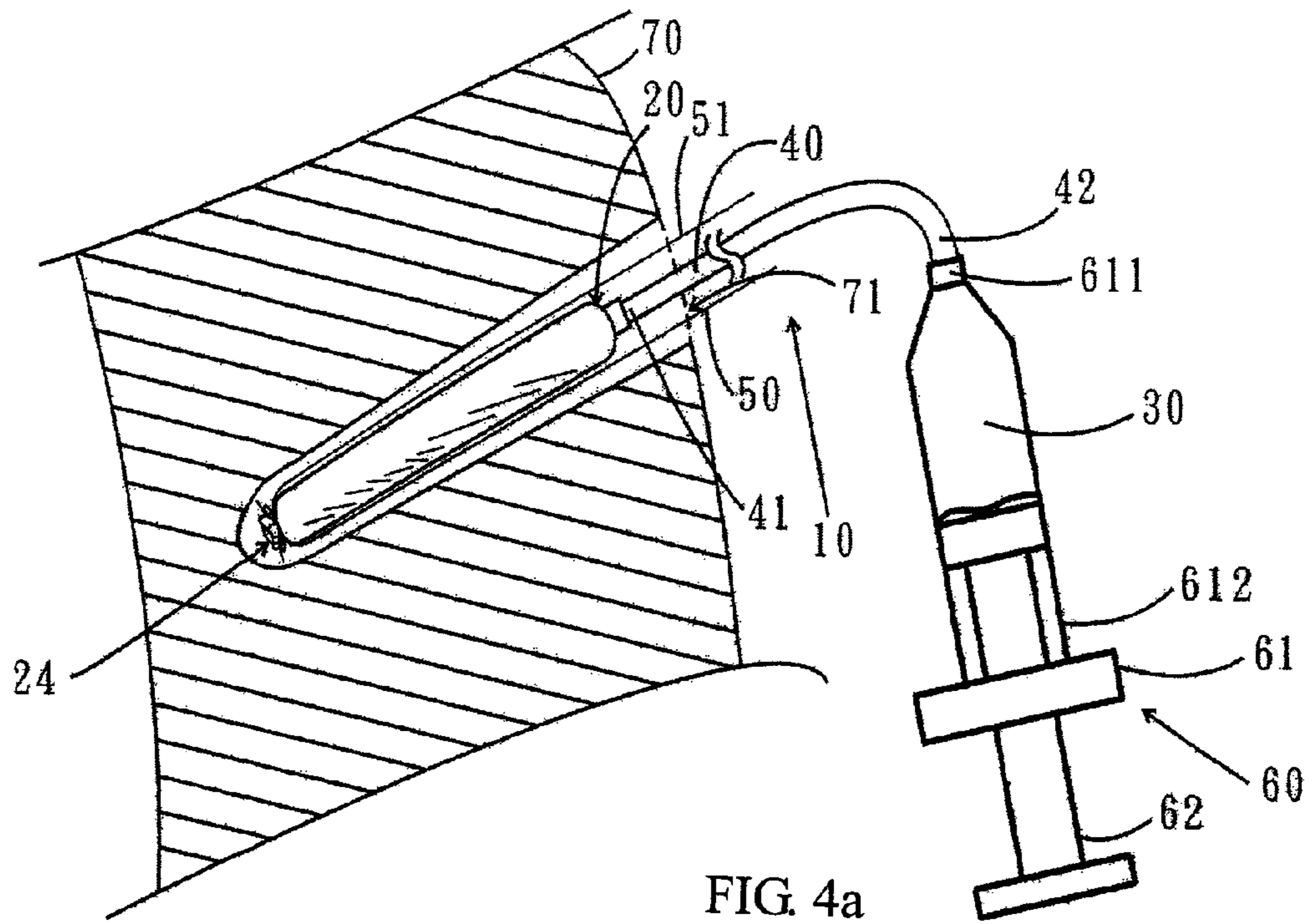


FIG. 3b



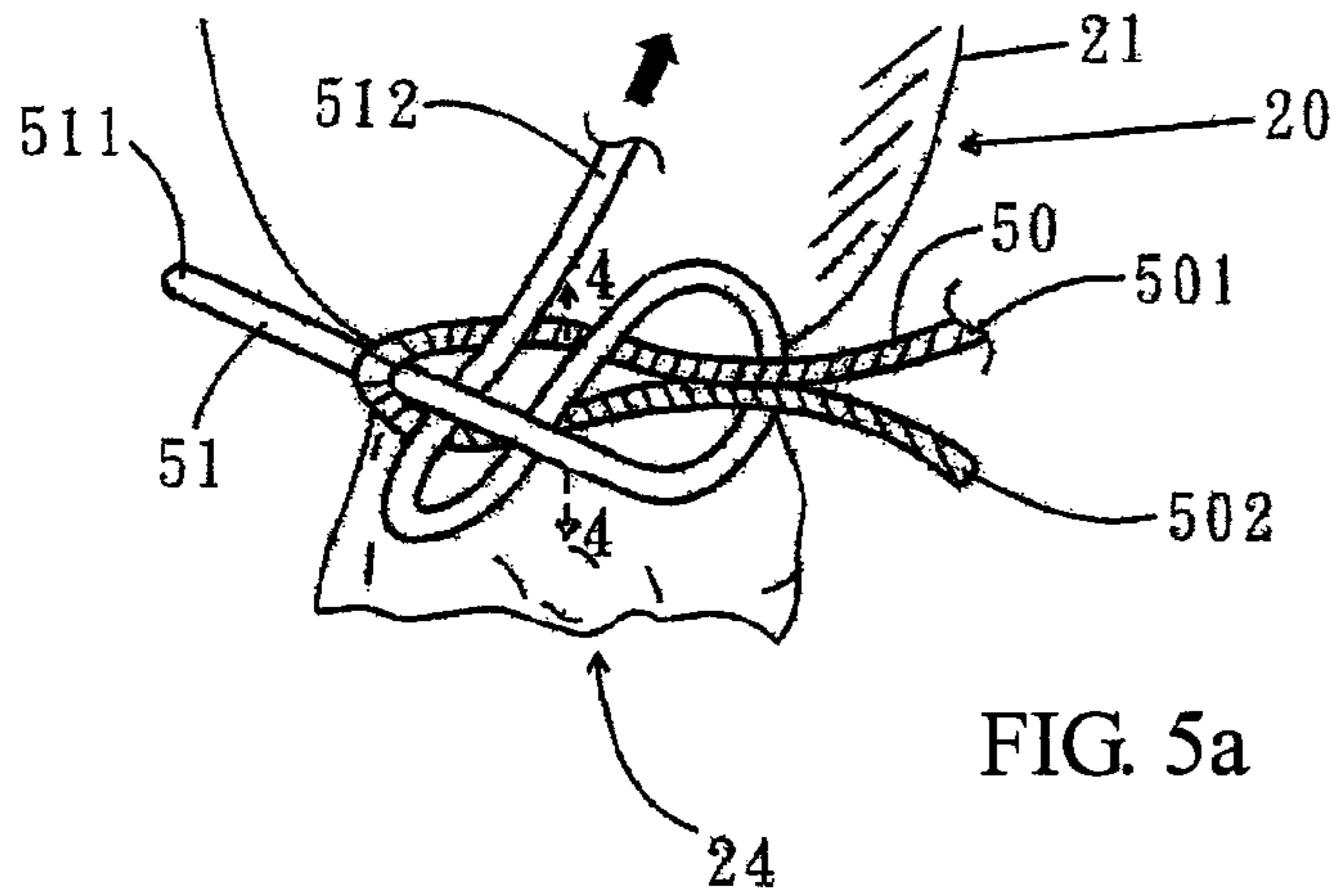


FIG. 5a

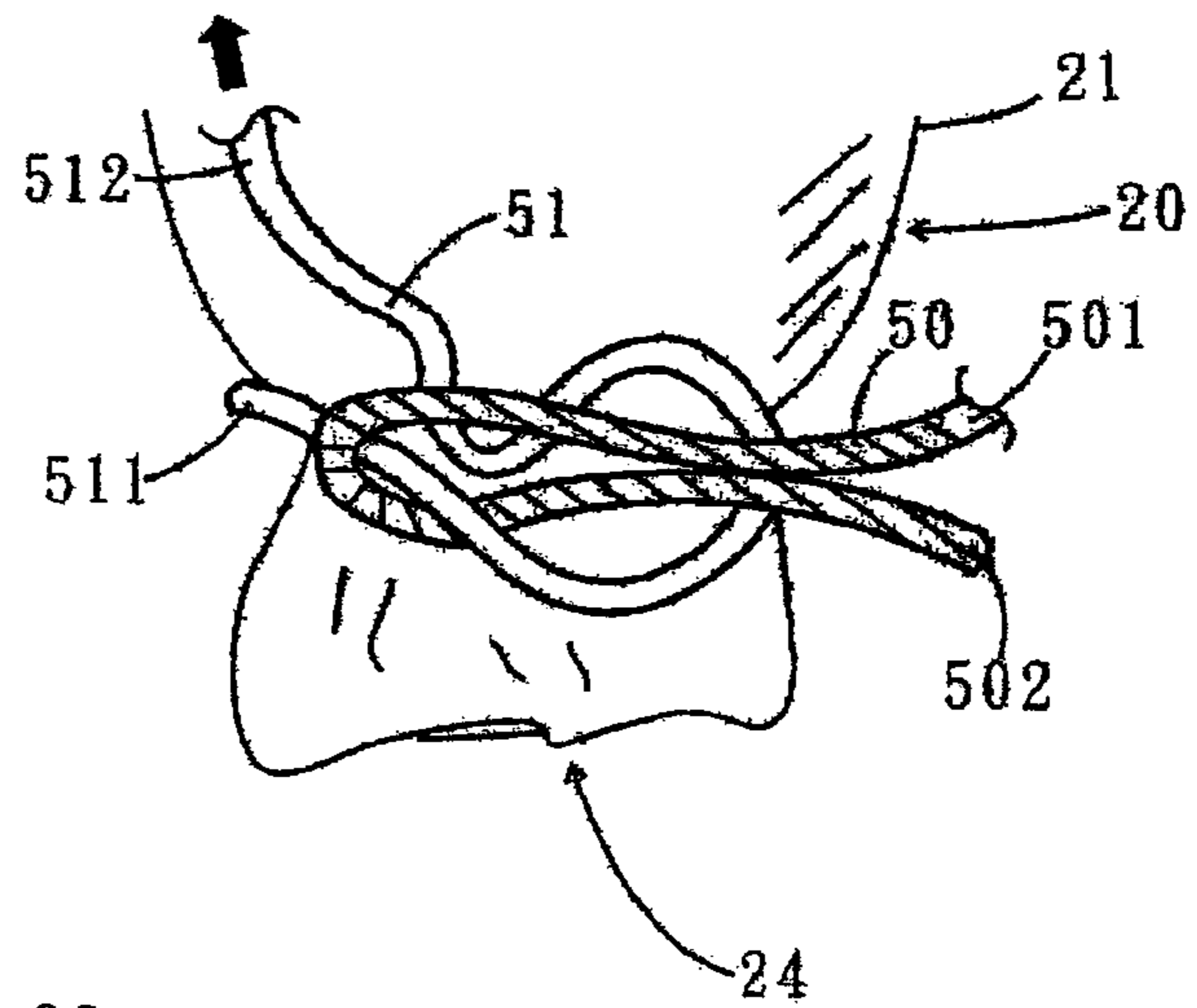


FIG. 5b

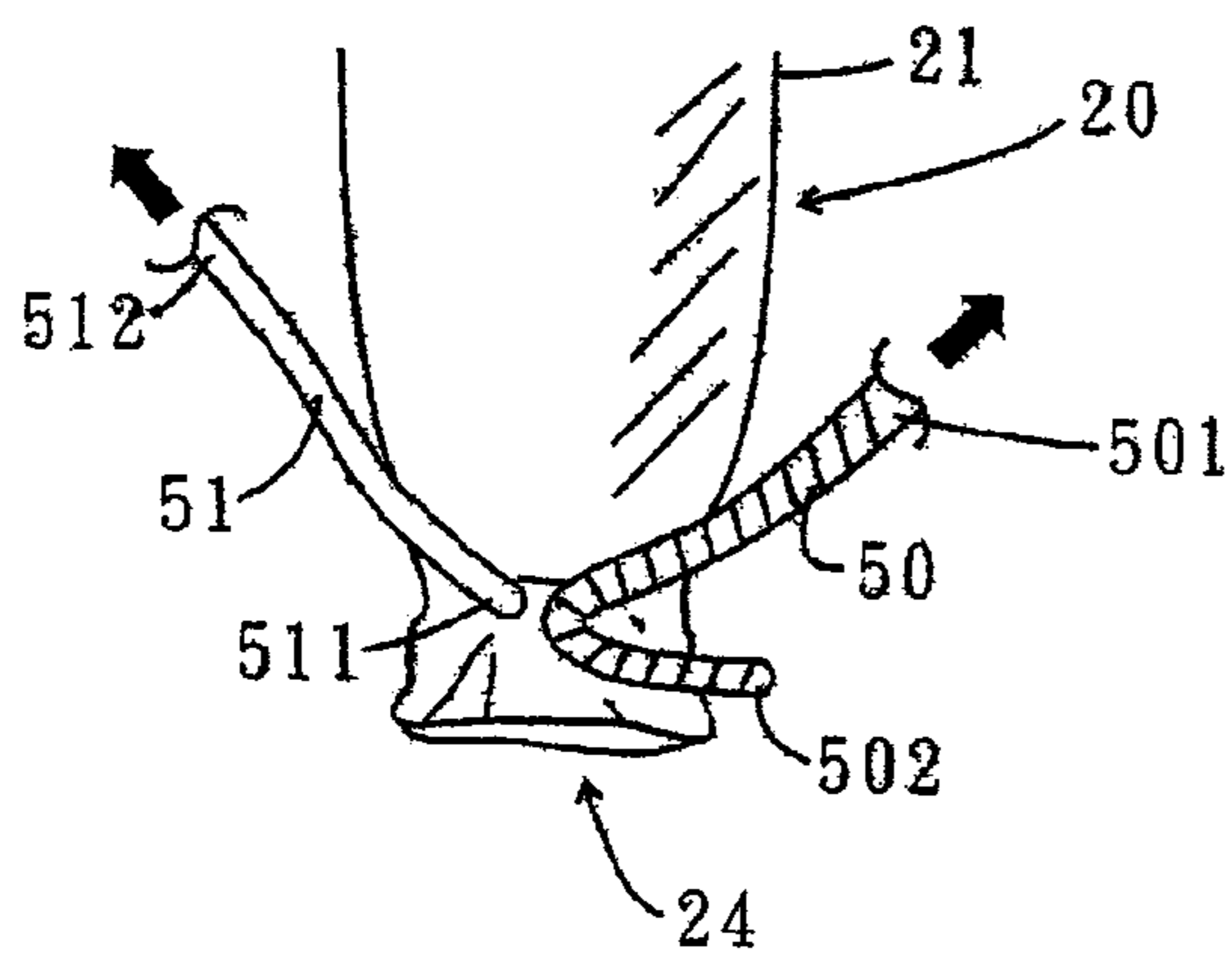


FIG. 5c

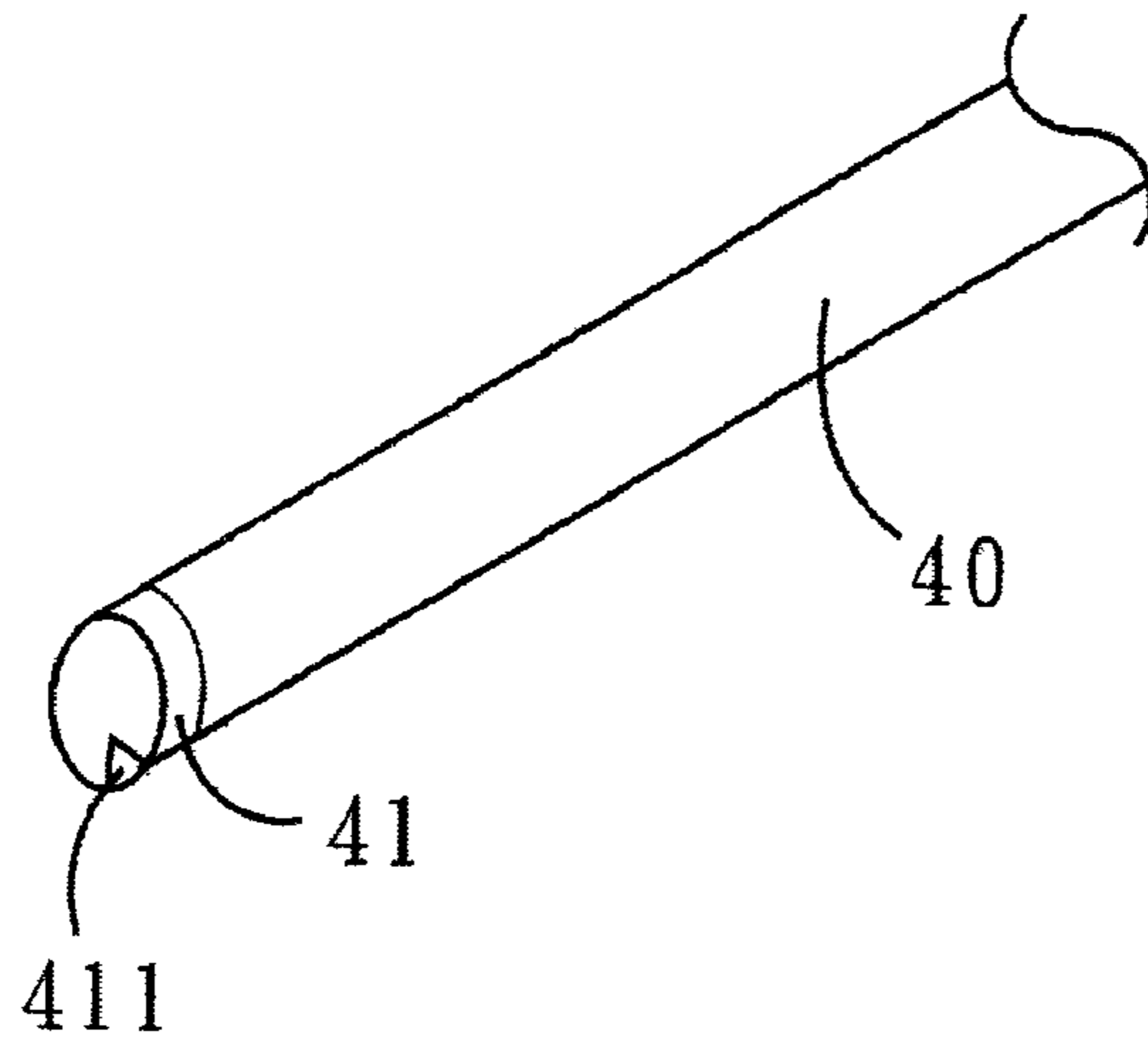


FIG. 6a

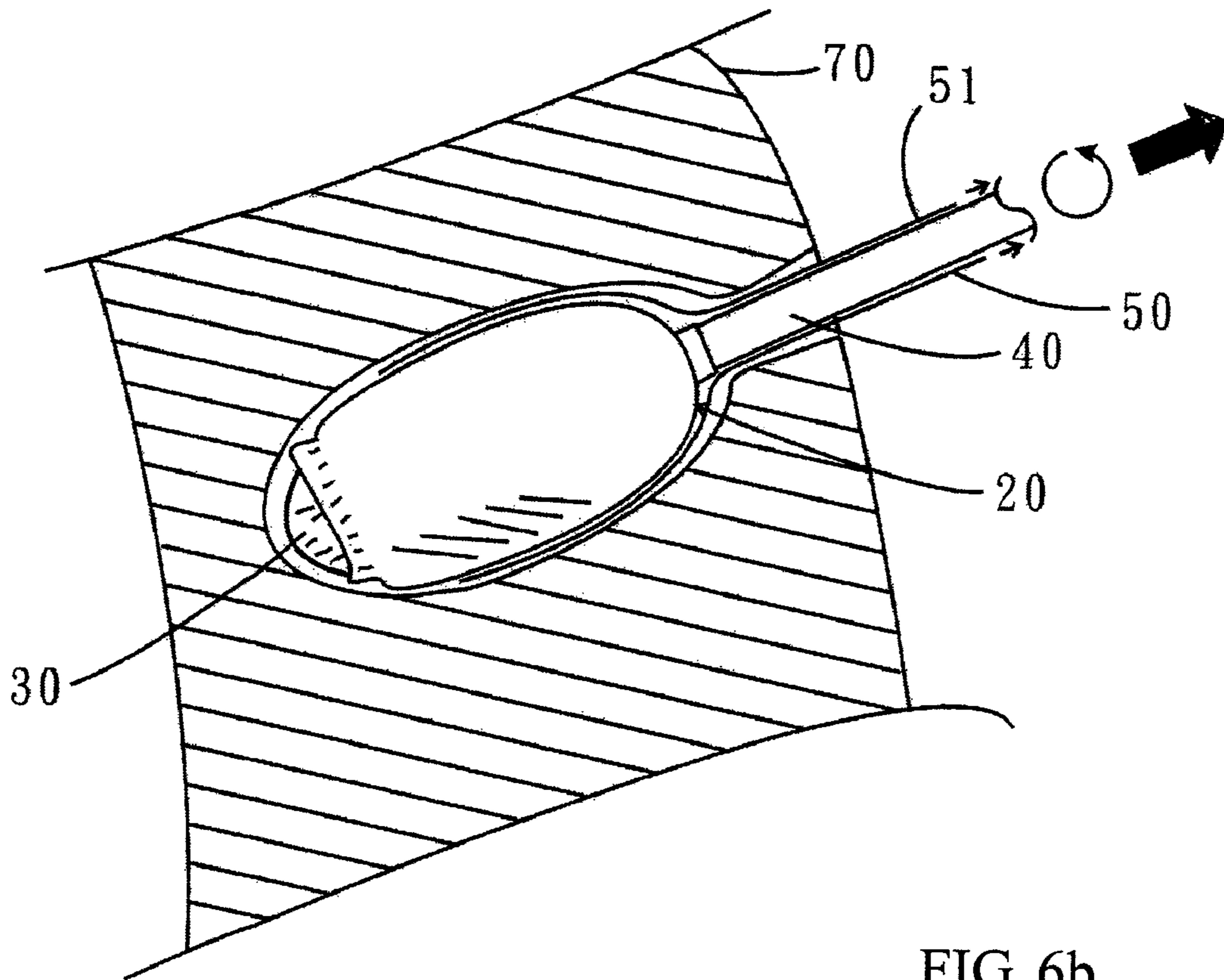


FIG. 6b

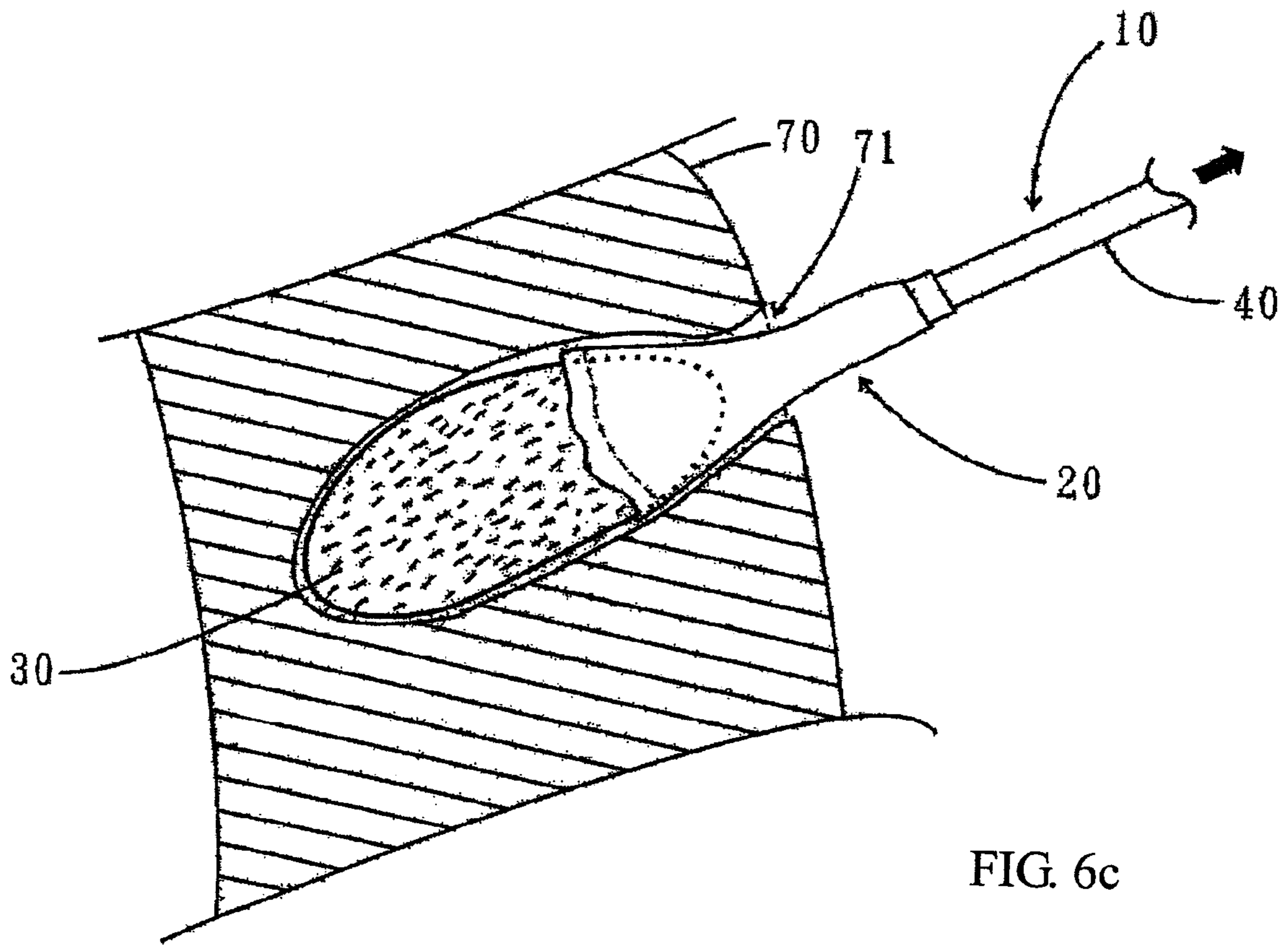


FIG. 6c

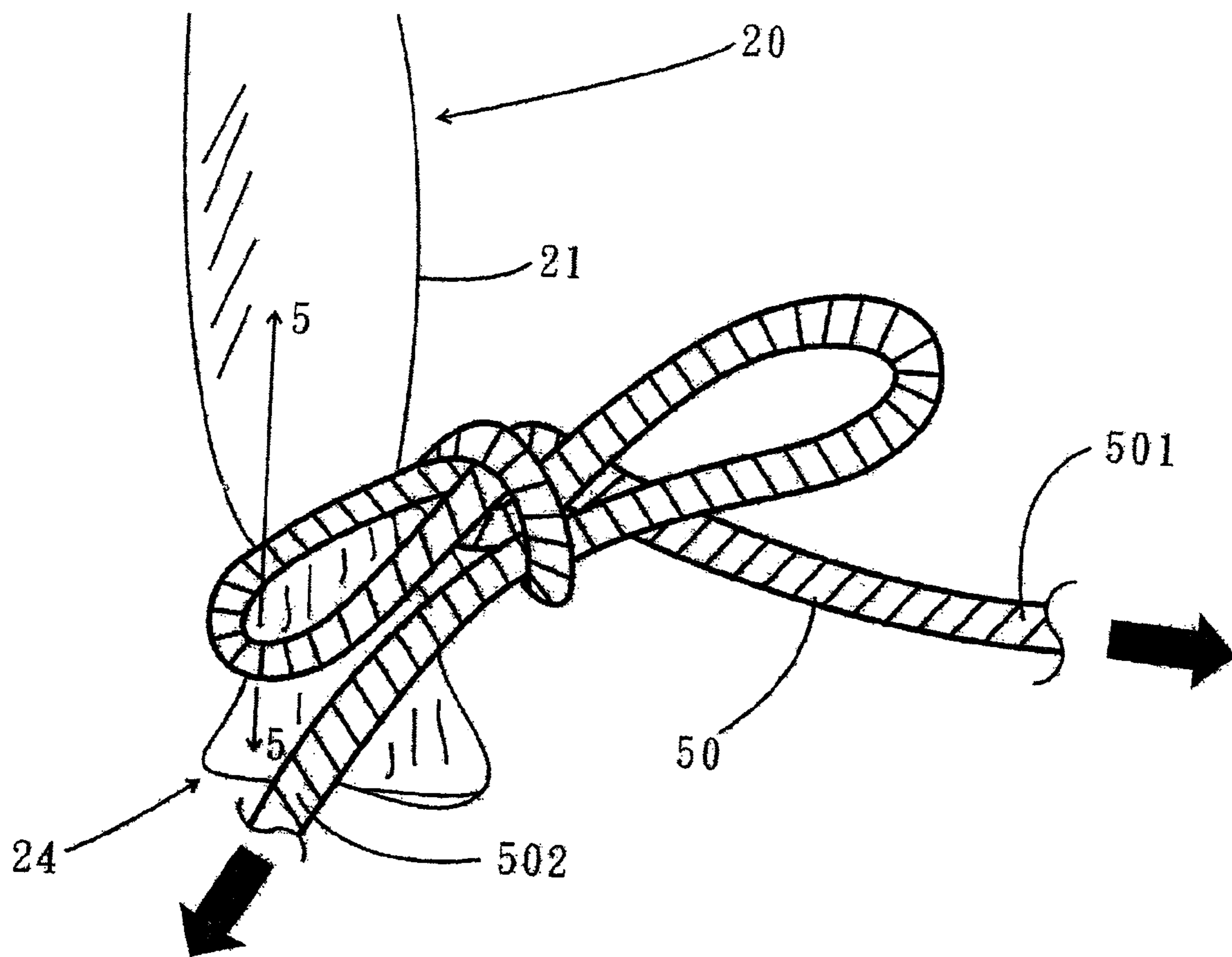


FIG. 7a

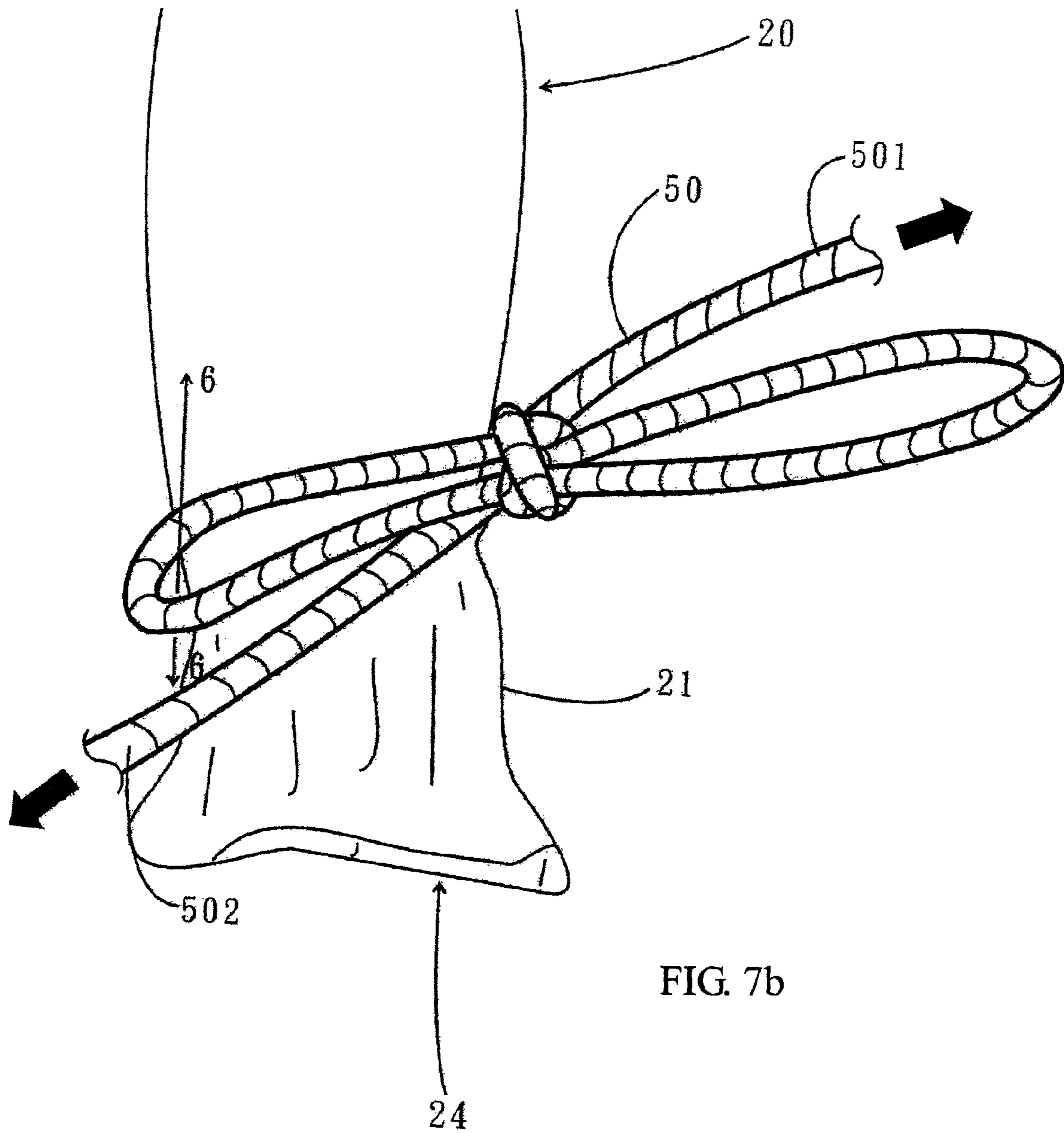


FIG. 7b

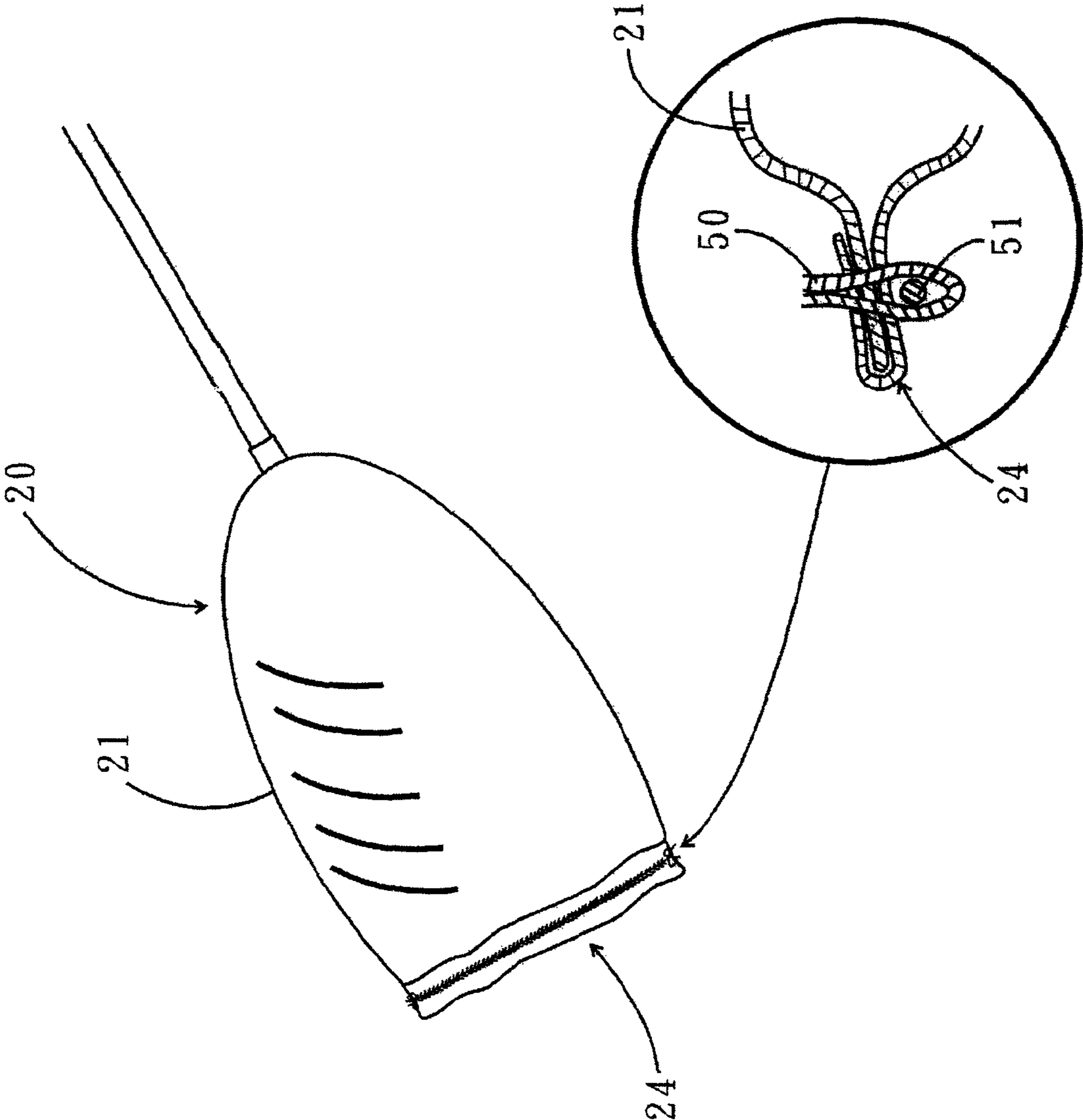


FIG. 8a

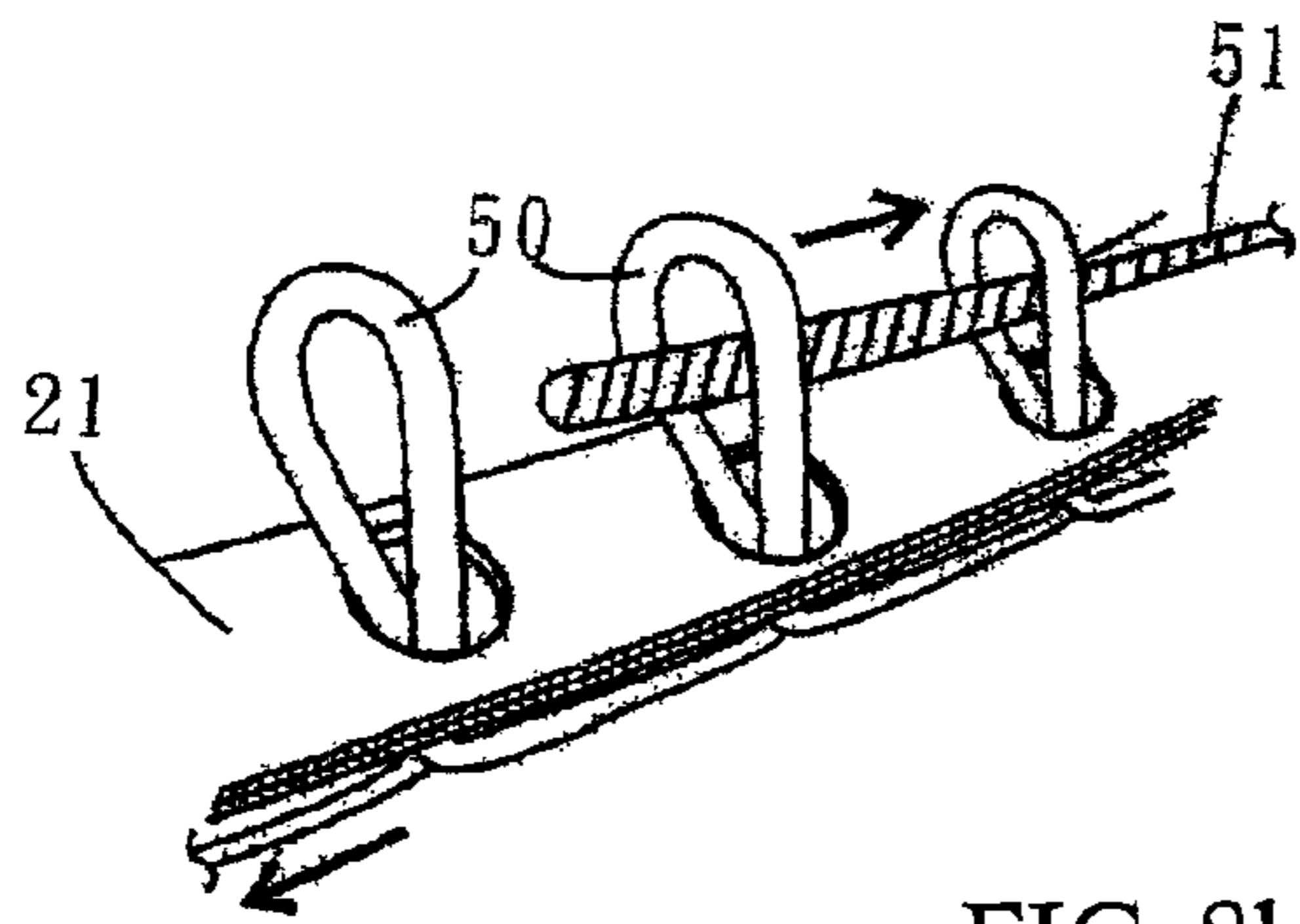


FIG. 8b

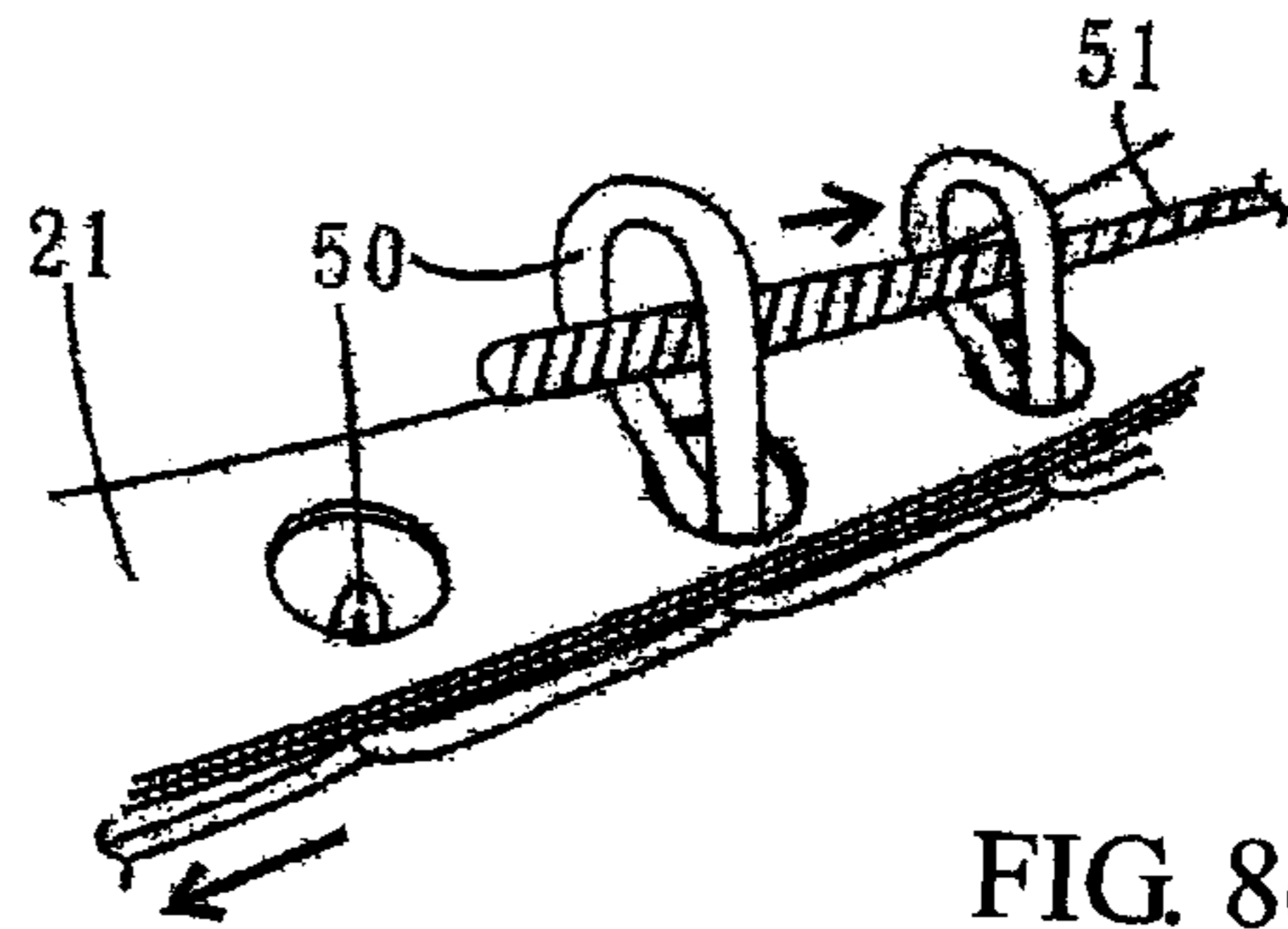


FIG. 8c

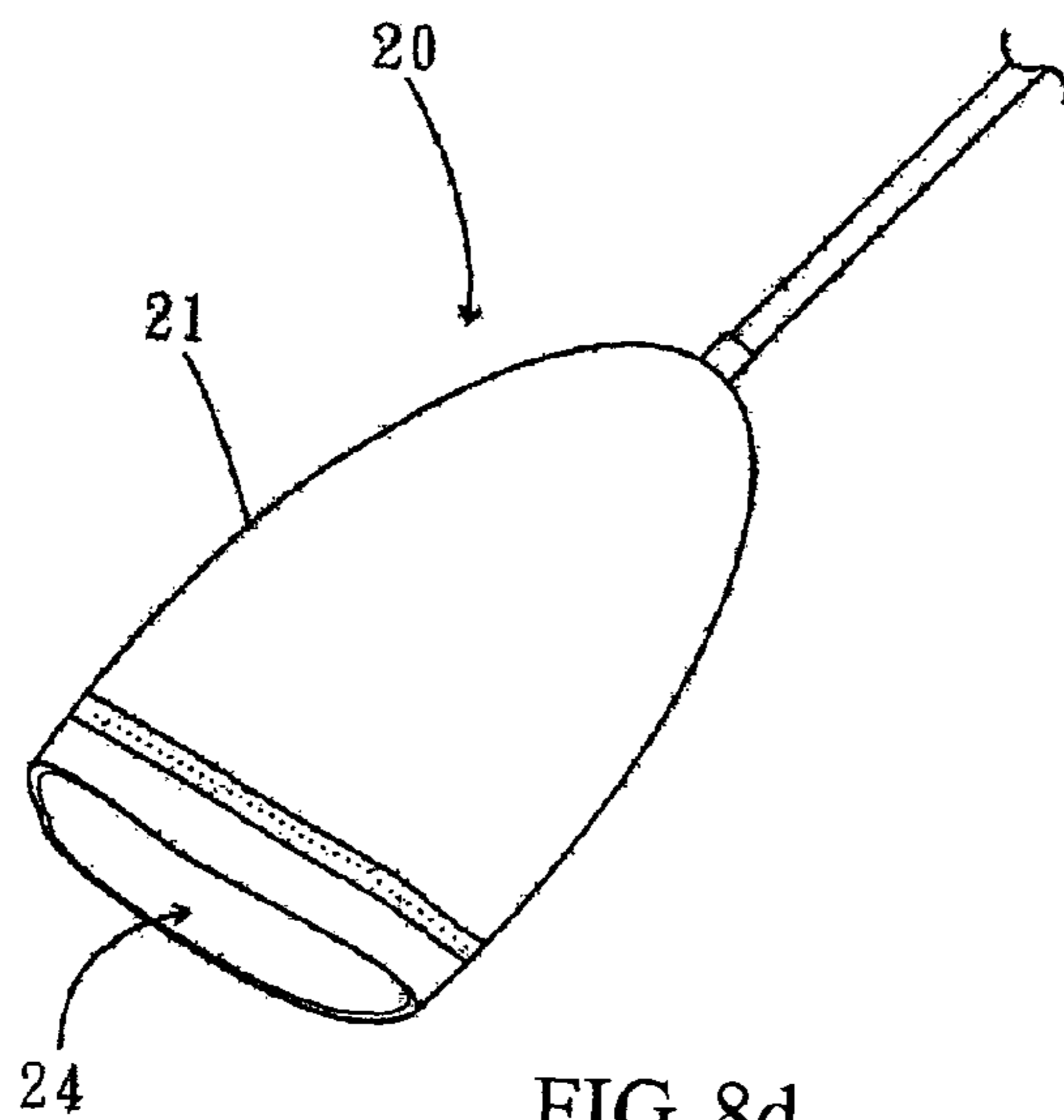


FIG. 8d

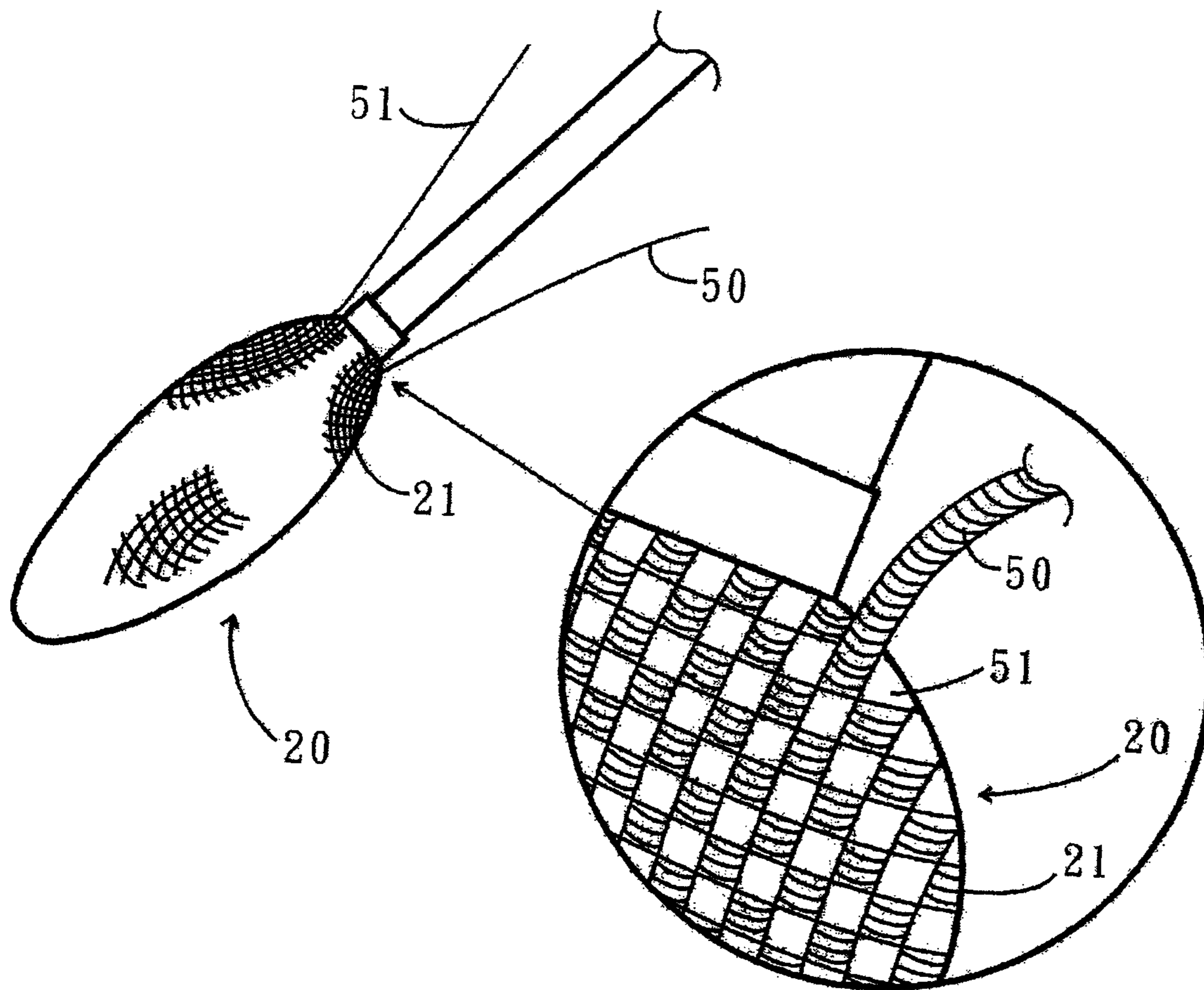


FIG. 9a

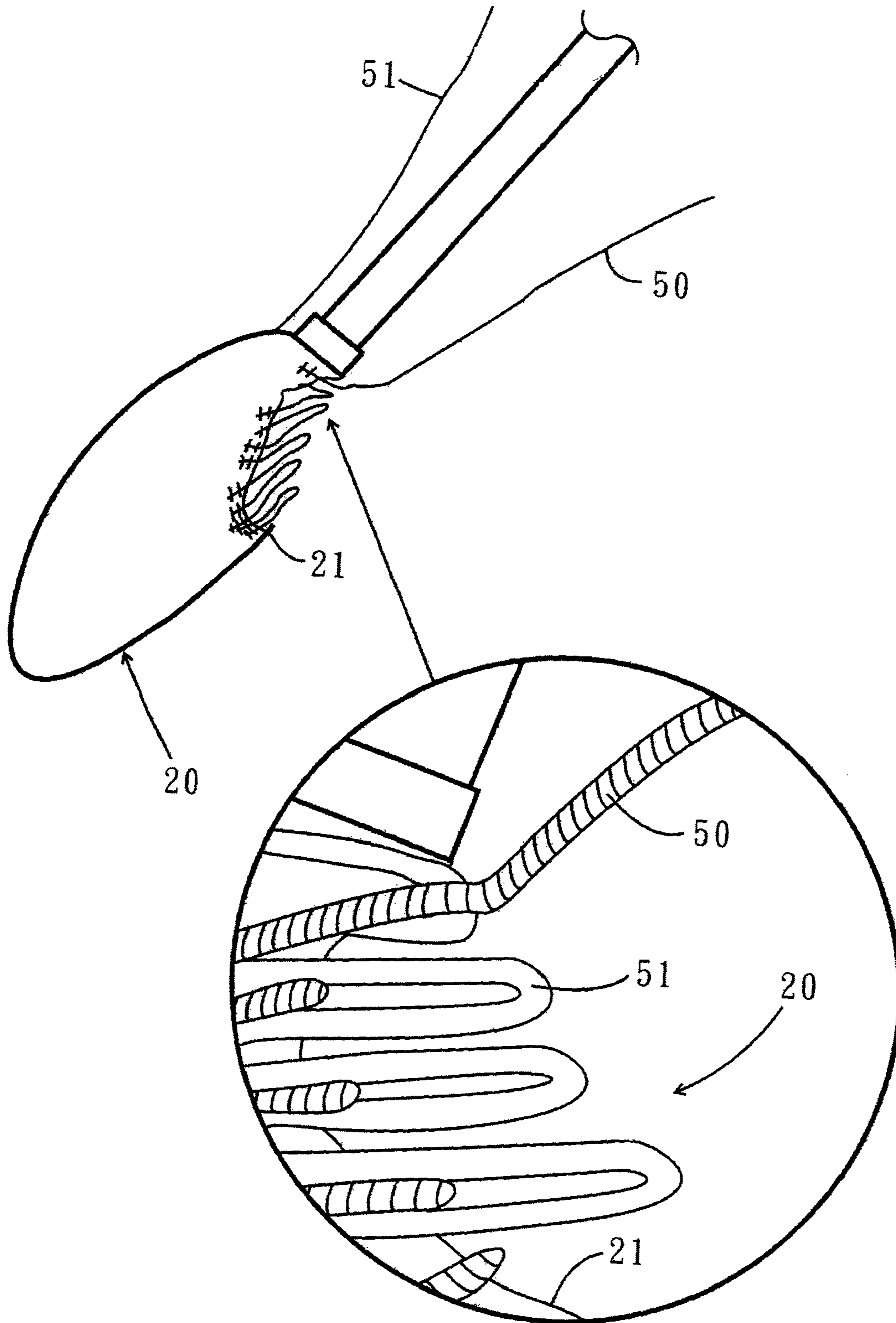


FIG. 9b

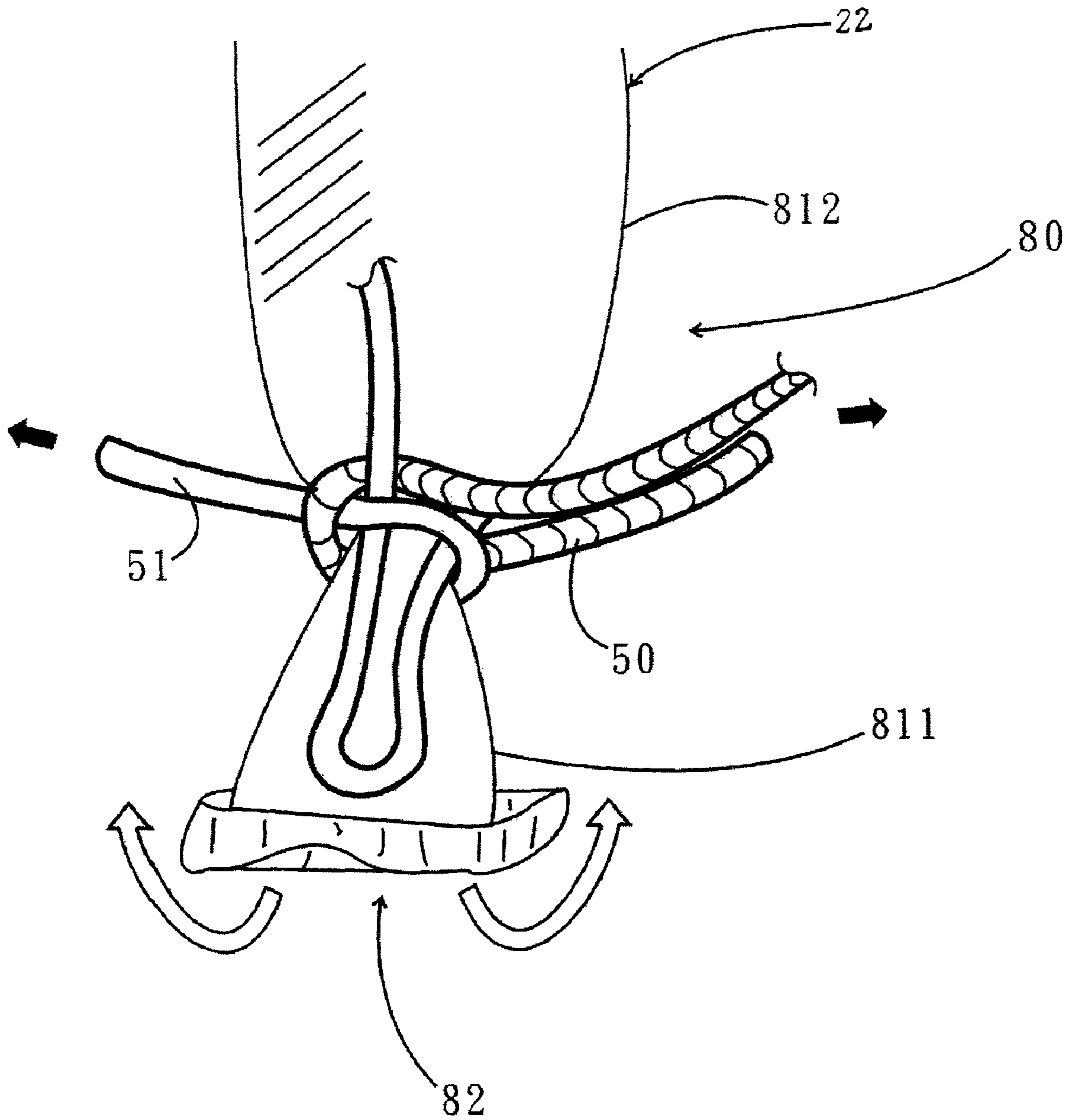


FIG. 10a

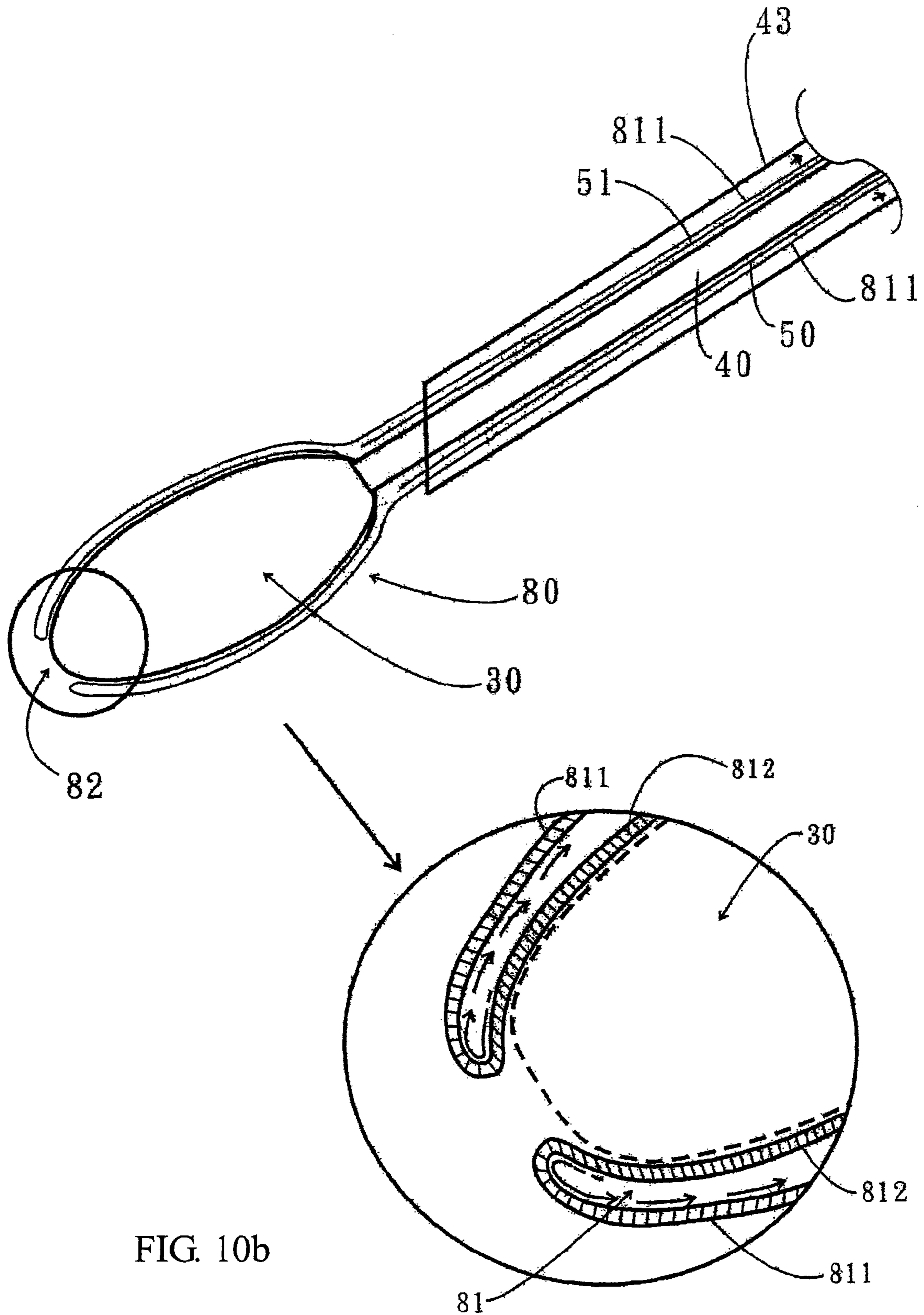


FIG. 10b

EXTRACTABLE FILLER FOR INSERTING MEDICINE INTO ANIMAL TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 10/651,988, filed on Sep. 2, 2003, now U.S. Pat. No. 7,175,627. This application claims the benefit of Taiwan Patent Application No. 92113774, filed on May 21, 2003.

FIELD OF THE INVENTION

The present invention relates generally to an instrument which is used in the restorative operation of animal tissue disorder. More specifically this surgical instrument can be used to insert a medical material into an animal tissue such that the instrument can be separated from the medical material and drawn out of the animal tissue so as to avert the possibility of tissue rejection.

BACKGROUND OF THE INVENTION

The surgical treatment of animal tissue disorder can be generally attained by one of three methods, which include the hypodermic injection of medicine, the balloon-insertion of medicine, and the filler-insertion of 15 medicine. For example, the U.S. Patent Nos. 5,972,015; 6,066,154; and 6,248,110B1 disclose respectively a method for treating bone tissue disorders, such as osteoporosis and vertebral compression fractures. The method involves the use of a balloon (made by the Kyphon Corp., U.S.A.) by which the tissue is expanded to facilitate the inserting of the 20 medicine. This balloon method is defective in design in that the medicine is apt to spread aimlessly in the tissue without boundary. Without containment, the medicine is not as effective and there is the possibility of injury to the surrounding tissues.

In order to prevent the drawbacks of the balloon method described above, the filler-insertion method is used to implant the medicine in animal tissue in such a way that the medicine is contained in the filler, and that both the medicine and the filler are implanted in the animal tissue. This filler-insertion method is often carried out in danger of the tissue rejection of the filler.

SUMMARY OF THE INVENTION

An extractable device for inserting a medicinal filling into an animal tissue, said device comprising:

a filling member comprising a flexible and permeable wall and provided with a holding portion, an injection port at one end of the holding portion, and an opening at another end of the holding portion;

one or more thread, each having one end for fastening releasably said opening of said holding portion in such a manner that said opening is leakproof; and

a pasty medicine to be injected into said holding portion via said injection port of said filling member in the wake of a process for inserting said filling member into the animal tissue whereby said pasty medicine solidifies in said holding portion of said filling member;

said opening of said holding portion being unfastened at the time when other end of said threads is pulled by an external force, thereby enabling said filling member to be extracted from the animal tissue so as to leave only said medicine in the animal tissue.

Preferably, wherein said flexible and permeable wall is of a one-layered or multi-layered construction.

Preferably, said holding portion of said filling member is integrally formed by said flexible and permeable wall into a body in the form of sac, bag, or ball.

Preferably, said pasty medicine is a mixture of a liquid and a medicinal powdered substance or medicinal granular substance.

Preferably, the device of the present invention further comprises an injection tool for injecting said pasty medicine into said holding portion via said injection port.

Preferably, said injection tool comprises a guide tube and a syringe, wherein one end of said guide tube is connected to said injection port of said filling member and another end of said guide tube is connected to said syringe in which said pasty medicine is held, so that said pasty medicine is able to be injected into said holding portion of said filling member by said syringe via said injection port and said guide tube.

Preferably, said flexible and permeable wall is a double-layer tubular wall having one end of an inner layer thereof being provided with said injection port of said holding portion, and having another end thereof being a folded double-layer end with said opening of said holding portion, wherein said medicine is released from said filling member by pulling a free end of an outer layer of the double-layer tubular wall to retreat the folded double-layer end, after said opening of said holding portion being unfastened.

Preferably, said one or more thread is between said inner layer and said outer layer of said double-layer tubular wall.

According to another aspect of the present invention an extractable device for inserting a medicinal filling into an animal tissue, said device comprises:

a filling member comprising a flexible and permeable wall which is formed of a plurality of threads by weaving, said filling member provided with a holding portion and an injection port at one end of the holding portion, said threads having a pull end extending out of said filling member; and

a pasty medicine to be injected into said holding portion via said injection port of said filling member in the wake of a process for inserting said filling member into the animal tissue whereby said pasty medicine solidifies in said holding portion of said filling member;

said flexible and permeable wall of said filling member being disintegrated at the time when the pull end of said threads is pulled by an external force, thereby enabling said filling member to be extracted from the animal tissue so as to leave only said medicine in the animal tissue.

The present invention also discloses a method for implanting a solidified medicine into an animal tissue comprising:

inserting a filling member in a hole of an animal tissue, said filling member comprising a flexible and permeable wall and provided with a holding portion, an injection port at one end of the holding portion, and an opening at another end of the holding portion, wherein one or more thread is provided and each having one end fastening releasably said opening of said holding portion in such a manner that said opening is leakproof;

injecting a pasty medicine into said holding portion via said injection port of said filling member, whereby said pasty medicine solidifies in said holding portion of said filling member; and

unfastening said opening of said holding portion by pulling other end of said threads, thereby enabling said filling member to be extracted from the animal tissue so as to leave only said solidified medicine in the animal tissue.

Preferably, the method further comprises fastening detachably an injection tool with said filling member, so that said

pasty medicine is injected into said holding portion via said injection tool. More preferably, said injection tool comprises a guide tube and a syringe, wherein one end of said guide tube is connected to said injection port of said filling member and another end of said guide tube is connected to said syringe in which said pasty medicine is held, wherein said pasty medicine is injected into said holding portion of said filling member by said syringe via said injection port and said guide tube.

The flexible wall of the filling member of the present invention is made of a biocompatible or biosynthetic material, such as rubber, elastic plastic, titanium, goat intestine, and the like. The flexible wall is provided with a plurality of pores and is therefore permeable. The flexible wall can be formed into an object in the form of sac, bag, ball, cylinder or rectangular column integrally or by joining separate pieces.

The filling member of the present invention may contain a ray imaging material, such as a metal wire, by which the precise position of the filling member can be easily located by a ray imaging system, such as an X-ray machine.

The flexible wall of the filling member of the present invention may be of a one-layered or multi-layered construction, depending on the particle size and the viscosity of the medicine. If the particle size of the medicine is relatively large, the flexible wall is preferably of a two-layered construction. If the viscosity of the medicine is relatively high, the flexible wall is also preferably of a two-layered construction. On the other hand, the flexible wall is preferably of a three-layered or four-layered construction under the circumstances that the particle size of the medicine is relatively small and that the viscosity of the medicine is relatively lower.

The features and the advantages of the present invention will be more readily understood upon a thoughtful deliberation of the following detailed description of the preferred embodiments of the present invention with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a sectional schematic view of the present invention.

FIGS. 2a-2c are schematic views illustrating the lashing of the opening of the holding portion of the filling member of the present invention.

FIG. 3a shows a longitudinal sectional view of a one-layered wall of the filling member of the present invention.

FIG. 3b shows a longitudinal sectional view of a multi-layered wall of the filling member of the present invention.

FIGS. 4a and 4b are sectional schematic view of the present invention at work.

FIGS. 5a-5c are schematic views illustrating the unlash of the opening of the holding portion of the filling member of the present invention upon completion of the injection of the medicine into the holding portion of the filling member.

FIG. 6a shows a schematic view of the connection tube of the implantation-injection apparatus of the present invention.

FIGS. 6b and 6c are sectional schematic views illustrating the process in which the filling member of the present invention is extracted from the animal tissue.

FIGS. 7a and 7b are schematic views illustrating that the opening of the holding portion of the filling member of the present invention is releasably lashed by a thread.

FIGS. 8a-8d are schematic views illustrating a process in which the opening of the holding portion of the filling member of the present invention is releasably lashed by two threads in conjunction with sewing.

FIG. 9a shows a schematic view of the flexible wall of the present invention being made of two threads which are releasably interlaced.

FIG. 9b is a schematic view to show that the two threads of the flexible wall, as shown in FIG. 9a, are unfastened.

FIG. 10a is a schematic view illustrating a process in which a double-layer wall of the holding portion of the filling member of the present invention is formed.

FIG. 10b illustrating a process in which the double-layer wall of the holding portion of the filling member of the present invention is retreated from the solidified medicine.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIG. 1, an extractable filler 10 embodied in the present invention comprises a filling member 20, a pasty medicine 30, a connection tube 40, and two threads 50 and 51. The filling member 20 is formed of a flexible wall 21 and is provided with a holding portion 22 and an injection port 23. The flexible wall 21 may be made of rubber with perforated holes or woven fabric with meshed pores. The pasty medicine 30 is injected into the holding portion 22 via the connection tube 40 and the injection port 23. The dotted line 3-3 shows a direction in which a section of the filling member 20 is taken.

As shown in FIG. 2a, the holding portion 22 of the filling member 20 is provided with an opening 24 opposite to the injection port 23 of the filling member 20. The opening 24 is lashed by two threads 50 and 51. The first thread 50 has a first end 501 and a second end 502, while the second thread 51 has a first end 511 and a second end 512. The two threads 50 and 51 are in fact fastened releasably to the flexible wall 21 near the opening 24. The way by which they are fastened together is not shown in the drawing.

The opening 24 of the holding portion 22 of the filling member 20 is securely tied up to prevent the medicine 30 from leaking out of the holding portion 22 by means of the two threads 50 and 51 which are releasably entangled in such a manner that the first end 511 of the second thread 51 is wound around the first thread 50. Upon completion of the winding process, the flexible wall 21 surrounding the opening 24 is located in a position between the two threads 50 and 51, as indicated by a dotted line 4-4 in FIG. 2b. Thereafter, both ends 501 and 502 of the first thread 50, and the first end 511 of the second thread 51 are respectively pulled rightward and leftwards at the same time, as illustrated in FIG. 2c. As a result, the opening 24 of the filling member 20 is leakproof.

The flexible wall 21 of the filling member 20 is of a one-layered construction, as shown in FIG. 3a, or of a multi-layered construction, as shown in FIG. 3b. The flexible wall 21 is provided with a plurality of pores 211 permeable to fluids. If the flexible wall 21 is of a multi-layered construction, the flexible walls 21 are laminated in such a way that the pores 211 are not corresponding in location to slow down the passage of the fluids.

As shown in FIGS. 4a and 4b, the filling member 20 is first inserted into a blind hole 71 of an animal tissue 70. The pasty medicine 30 is then injected into the holding portion 22 of the filling member 20 by a syringe 60 in conjunction with the connection tube 40. The filling member 20 is thus inflated by the medicine 30, as shown in FIG. 4b. The connection tube 40 has one end 41 which is connected with the filling member 20, and another end 42 which is connected to one end 611 of a barrel 61 of the syringe 60. A plunger 62 is slidably inserted into another end 612 of the barrel 61 in which the pasty medicine 30 is contained.

The pasty medicine **30** is a mixture of a liquid and one or more kinds of animal tissue drugs in the form of powder, granule, or colloid. The pasty medicine **30** is capable of solidification.

Upon completion of the solidification of the pasty medicine **30** in the blind hole **71** of the animal tissue **70**, the filling member **20** must be extracted from the blind hole **71** of the animal tissue **70**, so as to leave only the medicine **30** in the blind hole **71** of the animal tissue **70** to prevent the rejection of the filling member **20** by the animal tissue **70**. The extraction of the filling member **20** from the blind hole **71** of the animal tissue **70** involves a first step in which the second end **512** of the second thread **51** is pulled upward as indicated by an arrow in FIG. **5a**. As a result, the two threads **50** and **51** become loosened, as shown in FIG. **5b**. Thereafter, the first end **501** of the first thread **50** and the second end **512** of the second thread **51** are respectively pulled in a direction away from the opening **24** of the filling member **20**, as illustrated in FIG. **5c**. The opening **24** is thus unfastened completely.

As shown in FIG. **6a**, the connection tube **40** is provided in one end **41** with a pointed projection **411** inside the tube. As the connection tube **40** is slightly twisted, the solidified medicine **30** is severed by the pointed projection **411** of the connection tube **40**. The filling member **20** can be drawn out of the blind hole **71** of the animal tissue **70** by the connection tube **40**, as illustrated in FIG. **6b** and FIG. **6c**. As a result, only the medicine **30** is left in the blind hole **71** of the animal tissue.

The opening **24** of the filling member **20** may be fastened by only one thread **50**, as illustrated in FIGS. **7a** and **7b**. The thread **50** has a first end **501** and a second end **502**. With the thread **50**, a knot is formed to lash the opening **24** of the filling member **20** in such a manner that the flexible wall **21** of the opening **24** is surrounded by a loop as indicated by a line **5-5** in FIG. **7a**. With the second end **502** of the thread **50** remaining in the stationary state, the first end **501** is pulled to fasten the opening **24**. The opening **24** is unfastened by pulling the second end **502** of the thread **20**, thereby resulting in separation of the filling member **20** from the thread **50**.

The thread **50** can be also used to form a different knot, as shown in FIG. **7b**. The flexible wall **21** of the opening **24** of the filling member **20** is surrounded by a loop as indicated by a line **6-6** in FIG. **7b**. As the first end **501** of the thread **50** is pulled in a direction away from the filling member **20**, the opening **24** of the filling member **20** is lashed to become leakproof. The opening **24** of the filling member **20** is unlash to enable the filling member **20** to separate from the thread **50** by pulling the second end **502** of the thread **50**.

The opening **24** of the filling member **20** can be releasably fastened by sewing in conjunction with two threads **50** and **51**, as illustrated in FIGS. **8a-8d**. With the first thread **50**, a plurality of loops are formed. These loops are joined with the flexible wall **21** of the opening **24** by sewing. The second thread **51** is put through the loops of the first thread **50**. As the second thread **51** is pulled out of the loops of the first thread **50**, the first thread **50** becomes separated from the flexible wall **21** of the opening **24** of the filling member **20**, as illustrated in FIGS. **8b-8d**. As a result, the opening **24** is unfastened. Such a fastening as described above is similar to that which is commonly used to fasten the opening of a cement or flour bag.

As shown in FIGS. **9a** and **9b**, the flexible wall **21** of the filling member **20** is in fact a flexible fabric which is made of two threads **50** and **51** by weaving or knitting. The filling member **20** has a saclike form. The filling member **20** can be broken up in its entirety by pulling an exposed end of the thread **50**, as shown in FIG. **9b**. It must be noted here that the flexible fabric is provided with a plurality of meshes.

A further embodiment of the present invention is shown in FIG. **10a**, and FIG. **10b**, which is similar to the embodiment shown in FIGS. **1** to **2c**, except that a filling member **80** is formed of a double-layer wall **81** and the first thread **51** and second thread **52** are located between an inner layer **812** and an outer layer **811** of the double-layer wall **81**. As shown in FIG. **10a**, a flexible and permeable tubular wall is tied at an intermediate point thereof by the threads **50** and **51** at the beginning. The lower portion **811** of the tubular wall (will become an outer layer) is then rolled up, so that it is inside out and covering up the threads **50** and **51** and the upper portion **812** of the tubular wall (will become an inner layer). The rolled-up end of said double-layer wall **81** is provided with an opening **82** of the holding portion **22**, which is lashed by the two threads **50** and **51**. The opening **82** is unfastened by pulling the threads **50** and **51** the same way as shown in FIGS. **4a** to **4c**. As shown in FIG. **10b**, the rolled-up double-layer end is retreated from the solidified medicine **30** by pulling a free end of the outer layer **811** of the double-layer wall **81**, while one end of the inner layer **812** is connected to the connection tube **40** as an injection port of said holding portion **22** of the said filling member **80**, whereby said solidified medicine **30** is released from said filling member **80**. A working tube **43** is used to accommodate the connection tube **40**, the threads **50** and **51** and the free end of the outer layer **811** of the double-layer wall **81** of the filling member **80**.

The embodiments of the present invention described above are to be regarded in all respects as being illustrative and nonrestrictive. Accordingly, the present invention may be embodied in other specific forms without deviating from the spirit thereof. The present invention is therefore to be limited only the scopes of the following claims.

The invention claimed is:

1. An extractable device, comprising:

a flexible, permeable container having a proximal injection port configured to receive a solidifiable medicinal filling, and a previously created releasably closable distal opening configured to selectively allow delivery of the filling into a human tissue through an incision in the human tissue; and

at least one releasable thread configured to releasably close the distal opening to contain the filling within the container prior to solidification, and configured to allow the distal opening to reopen without permanently severing the container to enable the delivery of the filling into the human tissue through the incision after at least partial solidification,

the container having a first configuration and a second configuration, when the container is in the second configuration, the distal opening of the container is open and the container is disposed at least partially within the human tissue during a surgical procedure, the proximal injection port having a substantially constant size when the container is in the first configuration and the second configuration.

2. The device of claim 1, in which the thread is releasable upon application of at least one of an external pulling force or an external pushing force.

3. The device of claim 1, in which the container is sufficiently flexible for removal from the human tissue after solidification of the filling within the container.

4. The device of claim 1, in which the container is shaped like a bag.

5. The device of claim 1, in which the container is shaped like a ball.

6. The device of claim 1, in which the container comprises a tubular wall.

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7. The device of claim 1, in which the container comprises a holding portion integrally formed by a wall of the container.

8. The device of claim 1, in which the container comprises a single-layered wall.

9. The device of claim 1, in which the container comprises a multi-layered wall.

10. The device of claim 1, in which the container comprises an inner layer and an outer layer.

11. The device of claim 1, in which the container is formed of a plurality of threads.

12. The device of claim 1, in which the container is formed of a plurality of threads by weaving.

13. The device of claim 1, further comprising: an injection tool for injecting the solidifiable medicinal filling into the device through the proximal injection port.

14. The device of claim 13, in which the injection tool comprises a guide tube connected to the proximal injection port.

15. The device of claim 1, in which the at least one releasable thread has a length such that the at least one releasable thread extends from a location within the human tissue to a location outside of the human tissue when the container is in the second configuration.

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16. An extractable device, comprising:

a flexible, permeable container having a proximal inlet configured to receive a solidifiable medicinal filling and a previously created releasably closable distal outlet configured to allow subsequent delivery of solidified filling into a human tissue through an incision in the human tissue without permanently severing the container; and

at least one releasable thread configured to reduce leakage of the filling from the container,

the container having a first configuration and a second configuration, when the container is in the second configuration, the distal outlet of the container is open and the container is disposed at least partially within the human tissue during a surgical procedure, the proximal inlet having a substantially constant size when the container is in the first configuration and the second configuration.

17. The device of claim 16, in which the at least one releasable thread has a length such that the at least one releasable thread extends from a location within the human tissue to a location outside of the human tissue when the container is in the second configuration.

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